Supreme Court, U.S.
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No.

# In the Supreme Court of the United States

JOSEPH B. STAHL

Petitioner

vs.

NOVARTIS PHARMACEUTICALS CORP.

Respondent

## ON PETITION FOR WRIT OF CERTIORARI

To the United States Court of Appeals for the Fifth Circuit

## PETITION FOR WRIT OF CERTIORARI

JOSEPH BRANDEIS STAHL
*Counsel of Record for/& Petitioner*
Attorney at Law, La. Bar No. 12383
U.S. Supreme Court Bar since 4/20/70
801 Whitney Bank Building
228 St.Charles Avenue - Suite #801
New Orleans, LA 70130
(504) 525-4221

Riverside Printing, L.L.C., 4939 Tchoupitoulas, N. O., LA 70115, (504) 897-5000

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## QUESTIONS PRESENTED FOR REVIEW

i) 2 Circuit Conflicts

1) When measures to remedy the causes of casualties, undertaken subsequent to casualties by a party, **not** voluntarily but only after a controlling federal governmental agency by its superior authority ultimately forces the party to do so: Are such **in**voluntary, government-ordered subsequent remedial measures admissible into evidence to prove culpable conduct as being outside the purview of Federal Rules of Evidence, Rule 407's prohibition, as the Eighth Circuit held in *O'Dell v. Hercules, Inc.*, 904 F.2d 1194, 1204 (8th Cir.1990), or does Rule 407 apply to exclude them anyway, as the Fifth Circuit, initiating a quarrel with the Eight Circuit, contrarily held herein?

2) Where subsequent remedial measures—in the form of package-insert-warning information about dangers of prescription medication and the level of their risk, of which the manufacturing party had always known but never previously revealed—frontally contradict and impeach that party's allegations and summary judgment evidence both that the warning was already adequate before the inclusion of the additional information and that the drug is safe and innocuous: Are such inconsistent subsequent remedial measures admissible for impeachment, as every other federal Circuit has held in a multitude of cases, *e.g., Kenney v. Southeastern Pennsylvania Transp. Authority,* 581 F.2d 351, 356 (3rd Cir.1978), and as Federal Rules of Evidence, Rule 407, itself provides, or are such subsequent remedial measures inadmissible even to impeach evidence at summary judgment, as the Fifth Circuit, taking issue with every other federal Circuit, as well as with Rule 407 itself, contrarily

held herein?

ii) Circuit Court's Departure from Accepted, Usual Course of Judicial Proceedings

3) Where, as here, a federal Circuit Court of Appeals affirms summary judgment by inventing and putting a meritless argument into the non-moving party's mouth which non-mover **never** made, for the sole purpose of making rejection of that argument the reason for its decision, while sweeping under the rug and refusing to account for or even mention, as if non-existent, competent dispositive evidence on which non-mover **did** rely that inescapably countervails summary judgment and as to admissibility of which there was never any dispute—thereby also sanctioning the District Court's similar refusal to account for such evidence: Is such dishonesty and irresponsibility a far enough departure from the accepted and usual course of judicial proceedings to call for exercise of the Supreme Court's supervisory power?

iii) Circuit Court Decision Conflicting with Supreme Court Decisions

4) Where, as here, a Circuit Court of Appeals affirms a Federal Rules of Civil Procedure, Rule 56(c) summary judgment by a) *counting* up and *weighing countervailing evidence* that it held to be relevant and admissible and that it found to frontally contradict mover's summary judgment evidence, and finding, as though at a trial, that it was *outnumbered* by and of insufficient *weight to overcome* mover's evidence, thereby b) *resolving evidentiary conflicts and issues of fact* at the summary judgment stage, specifically transgressing the Supreme Court's prohibition thereof at summary judgment in *Anderson v. Liberty Lobby,*

*Inc.*, 477 U.S. 242, 255, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986), and *Matsushita Electric Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986): Does such violation of Supreme Court precedent warrant Supreme Court review and reversal?

## LIST OF ALL PARTIES TO THE PROCEEDING

Petitioner: JOSEPH B. STAHL, an individual Louisiana citizen

Respondent: NOVARTIS PHARMACEUTICALS CORP., a Swiss corporation, and its corporate relations and predecessors including Sandoz Pharmaceuticals Corp. and Ciba-Geigy Corp.

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**PETITION FOR WRIT OF CERTIORARI**
**To the United States Court of Appeals for the Fifth Circuit**

To the Honorables the Chief Justice and the Associate Justices of the Supreme Court of the United States:

Petitioner, JOSEPH B. STAHL, prays that the United States Supreme Court issue a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit.

**CITATIONS OF OFFICIAL REPORTS OF OPINIONS & ORDERS**

Petitioner seeks review of the Judgment of the United States Court of Appeals for the Fifth Circuit in this cause, *Stahl v. Novartis Pharmaceuticals Corp.*, 283 F.3d 254

(5th Cir.2002), and of its *per curiam* Order denying rehearing without reasons, 2002 U.S.App. LEXIS 6008 (5th Cir.March 15, 2002).

## BASIS FOR JURISDICTION

Judgment of the United States Court of Appeals for the Fifth Circuit, sought to be reviewed, was entered on February 13, 2002. The Fifth Circuit's *per curiam* Order denying rehearing without reasons was entered on March 15, 2002.

Jurisdiction of the United States Supreme Court is invoked pursuant to the provisions of:

1) Title 28, United States Code, Section 1254(l), permitting grant of Certiorari upon petition by a party to a civil action after rendition of judgment by a United States Court of Appeals; and

2) Rules of the Supreme Court of the United States, Part III, Rule 10(a)&(c), permitting grant of Certiorari where a United States Court of Appeals has:

i) entered a decision in conflict with the decisions of other United States Courts of Appeals on the same important matter;

ii) so far departed from the accepted and usual course of judicial proceedings, and additionally sanctioned such a departure by a lower court, as to call for an exercise of the Supreme Court's supervisory power; and

iii) decided an important federal question in a way that conflicts with relevant decisions of the Supreme Court.

## 2 STATUTES INVOLVED

1) Federal Rules of Evidence, Rule 407, provides:

> "When, after an injury or harm caused by an event, measures are taken that, if taken previously, would have made the injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove negligence, culpable conduct, a defect in a product, a defect in a product's design, or a need for a warning or instruction. This rule does not require the exclusion of evidence of subsequent measures when offered for another purpose, such as proving ownership, control or feasibility of precautionary measures, if controverted, or impeachment."

2) Federal Rules of Civil Procedure, Rule 56(c), provides in pertinent part:

> "The [summary] judgment sought shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." (Brackets added.)

## STATEMENT OF CASE *RE* CIRCUIT CONFLICT OVER F.R.Ev., Rule 407

Jurisdiction in the court of first instance, the United States District Court for the Eastern District of Louisiana, was based on 28 U.S.C. 1332(2) diversity, etc.

Starting in the 1980s, Respondent developed, tested and manufactured the prescription anti-fungal agent Lamisil Tablets ("Lamisil") (not to be confused with Lamisil AT, a topical, non-prescription ointment), which has no utility besides relief of cosmetic fingernail and toenail fungus. Respondent introduced it in Europe and Asia in 1989, and, with U.S. Food and Drug Administration ("FDA") approval, in the U.S. in October 1996, where it hired an advertising agency to tout it directly to the public in late-night TV ads.

Lamisil was prescribed for the then 61-year-old Petitioner on April 3, 1998 for mild fungus of his left big toenail and almost killed him by April 27, 1998, his 24th day on the drug, permanently damaging his liver severely and extensively with a case of toxic chemical cholestatic hepatitis and ruining what had been till then his unusually healthy life, in which, according to the most current bloodwork, on October 10, 1995, the then-59-year-old Petitioner never had pre-existent liver disease.

Petitioner had not undergone any baseline or current liver-function blood testing during his 24 days on Lamisil because Respondent's 1997 Lamisil literature, still in effect at prescription for Petitioner, established a medical monitoring regimen mandating delay in commencement of such testing till the 7th week on Lamisil, and Respondent's detail people had also categorically instructed Petitioner's prescribing physician not to test blood until the 7th week, notwithstanding Respondent's actual knowledge that 17 people had been killed by Lamisil, some in as little as little as 5 days, others in 2 or 4 weeks, but all 17 in less than 6 weeks, of taking Lamisil. Respondent concealed that information, correctly anticipating that no doctor would prescribe, and no

patient take, for mere superficial blemish, an elective cure involving the expense and annoyance of bloodwork on as early and frequent a basis as necessary to warn, in time to discontinue Lamisil without serious or permanent harm, that Lamisil was starting to cause liver damage.

Petitioner had no idea that his severe illness, and the dark brown urine and white stools that appeared with its onset on his 24th day on Lamisil, April 27, 1998, were hepatitis symptoms or from Lamisil, which he continued to take for 4 *more* days (Respondent's Lamisil warning had not yet mentioned dark urine and pale stools as either a reason to stop taking Lamisil or even to start blood testing.), suffering yet *further damage*, until May 1, 1998, when a physician told him to stop because Lamisil had caused him to suffer toxic chemical cholestatic hepatitis.

Petitioner sued Respondent under the Louisiana Products Liability Act ("LPLA"), La.Rev.Stat. Ann. Sec. 9:2800.52 *et seq.,* asserting, *inter alia,* inadequacy thereunder of Respondent's Lamisil warning. The District Court dismissed the action on summary judgment that the warning was adequate, and the Fifth Circuit affirmed, conceding, however, that Louisiana courts, interpreting the LPLA, have controllingly held that "a prescription drug warning is **not adequate** as a matter of law simply because the warning label contains a clear and unambiguous reference to the adverse reaction suffered by the plaintiff," because it must **also** be "**worded strongly enough to** adequately **inform** [the prescribing physician] of **the actual level of risk** involved." (Brackets, boldface added.) 283 F.3d at p. 267.

But Respondent's pre-FDA-changed literature not only failed to provide **any** information as to **the actual level of risk** of the hepatitis posed by Lamisil but went so

far as to lie and conceal information about, so as to downplay, that level of risk and blindfold and dupe doctors into wholesale, indiscriminate prescription of Lamisil.

To begin with, Respondent's 1997 literature merely referred to "symptomatic idiosyncratic hepatobiliary dysfunction including cholestatic hepatitis" as something of which "rare cases" had only been "reported," not even as having been **caused** *by Lamisil.* This vague reference does not reveal that Lamisil **causes** and **can cause** severe, critical, fatal or **any** form of **cholestatic hepatitis,** for, as a matter of simple logic, vindicated by repeated judicial decision, and as Petitioner's prescribing physician testified (quoted *infra*, p. 19), the mere statement that such cases of hepatobiliary dysfunction including cholestatic hepatitis *had only been* ***reported,*** and then just rarely, without any accompanying statement of a **causal** link to *Lamisil,* leaves doctors in the dark to guess whether such merely "reported" hepatobiliary dysfunction including cholestatic hepatitis: *pre-existed* administration of Lamisil; was caused *during* administration of Lamisil by some *other* agency besides Lamisil; *or* was caused by Lamisil itself. *See, e.g., Salmon v. Parke Davis & Company,* 520 F.2d 1359, 1361-63 (4th Cir.1975), *Givens v. Lederle,* 556 F.2d 1341, 1345 (5th Cir. 1977), and *Tompkin v. American Brands,* 219 F.3d 566, 572-73 (6th Cir.2000), those 3 cases all making that exact point as a matter of mere logic without reference to any particular state's law, namely, that mere mention of existence of a reported adverse event without **causally** linking it to the drug will leave doctors uninformed of any connection to the drug at all or at best aware only of some vague, unspecified level of risk, *i.e.,* not informed of the **"actual level of risk"** acknowledged by the Fifth Circuit to be *required* by Louisiana law, 283 F.3d at p. 267.

The Fifth Circuit nevertheless, after stating that "the 1997 package insert specifically indicated that 'Rare cases of symptomatic [*sic*, omitting Respondent's dishonestly included 'idiosyncratic'] hepatobiliary dysfunction including cholestatic hepatitis have been reported' and that 'treatment with Lamisil ... Tablets should be discontinued if hepatobiliary dysfunction develops,' " 283 F.3d at 266, held that that so-called "specifically indicated" **non-specific** nebulous blather (and the nonsense about discontinuing Lamisil after the horse is already out of the barn and it's too late because one ***already*** *has suffered the rarely reported adverse event of hepatobiliary dysfunction)* somehow complies with Louisiana's requirement to warn of **the actual level of risk.**

But all the foregoing is merely background to the Fifth Circuit's conflict with the Eighth Circuit.

The crux of it is that Respondent **knew**, both from its own pre-clinical, clinical and post-marketing trials conducted from 1989 to 1995, and from medical journal literature during and after that time up to the April 3, 1998 prescription of Lamisil for Petitioner, **but failed to warn,** *before* prescription for Petitioner, and only later warned *after* the FDA **forced** Respondent to do so under threat of withdrawal of Lamisil from the U.S. market, that **the actual level of risk** posed by Lamisil can only be scientifically communicated to the learned intermediary medical profession by inclusion of the following **additional, essential** information:

1) The **actual level of risk** of Lamisil is that Lamisil **can and does cause severe, critical and fatal** forms of symptomatic hepatobiliary dysfunction including cholestatic hepatitis.

2) The **actual level of risk** of Lamisil, being **the severe, critical and fatal level,** requires both pre-treatment, and earlier than 7th-week, liver-function blood testing during Lamisil therapy, because **within as few as 5 days, 2 weeks and 4 weeks of taking Lamisil** 22 patients suffered **liver failure,** of whom 17 met **death** and 2 had **need of liver transplant,** from **very severe levels** of hepatobiliary dysfunction in the form of cholestatic hepatitis **caused by** *Lamisil* (such that Respondent's wait-till-7th- week blood-monitoring instruction in its 1997 literature, still in effect at prescription for Petitioner, was dangerously, even fatally, misleading).

3) The **actual level of risk** of Lamisil-induced cholestatic hepatitis being **the severe, critical and fatal level,** therefore appearance of jaundice, dark urine and/or pale stools, which are symptoms of **already existing** cholestatic hepatitis, is a reason to **immediately stop taking** Lamisil (such that the *absence* of an instruction, to immediately stop taking Lamisil upon appearance of discolored products, in Respondent's 1997 literature, still in effect at prescription for Petitioner, was the cause of Petitioner's continuing to take Lamisil, to his *further* detriment, *even after* appearance of his dark urine and pale stools). And

4) The **actual level of risk** of Lamisil is accurately measured by reference to the fact that it is **inherently hepatotoxic (poisonous to the liver) in all patients,** both those without any, and those with, pre-existent liver disease (and *in*accurately measured by reference to the claim in Respondent's 1997 literature, still in effect at prescription for Petitioner, that adverse reactions to Lamisil are merely "idiosyncratic," as if their cause were some patient flaw instead of, as Respondent knew to be true, *Lamisil's* **inherent hepatotoxicity).**

Respondent's 1997 Lamisil literature still in effect at the April 3, 1998 prescription for Petitioner not only failed to warn of any of the foregoing, but, in a Madison-Avenue- ad-agency masterpiece of guile, deceit and trickery, described adverse events to Lamisil as only "mild."

It is axiomatic, and has been uniformly held judicially, that changing a drug warning establishes that the pre-change warning was inadequate in every respect affected by the change; *see, e.g., Love v. Wolfe,* 249 Cal.App.2d 822, 58 Cal.Rptr. 42, 48-49 (1967).

**After** Lamisil had been prescribed for, nearly killed, and has left Petitioner with severe and extensive liver damage condemning him to a daily round of excruciating tortures that amount to a slow death sentence, **the FDA** on January 4, 1999 and May 8, 2001, **ordered** Respondent to add the information numbered 1)-4) above that remedies enough inadequacies of its 1997 warning to have convinced doctors to stop prescribing this Lamisil brand of poison, and Respondent, under duress, added that information only after having been ordered to by the FDA. The Fifth Circuit mentioned only the first of the 2 January 4, 1999 warning changes, namely, addition of the words "jaundice, dark urine or pale stools," but added by Respondent only as a reason to start blood tests, not yet as a reason to discontinue Lamisil (The other January 4, 1999 warning change was addition of the words "and very rarely liver failure," added by Respondent as a further risk.), 283 F.3d at p. 270, n. 10, although all of **both** the *May 8, 2001 changes* (constituting the *rest* of the above-numbered items 1)-4)) **and** the ***two*** *January 4, 1999 changes* were of record in both the Fifth Circuit pursuant to Federal Rules of Appellate Procedure, Rule 28(j) and Fifth Circuit Rule 28.5 and, previously, in the District Court.

Circuit Conflict 1: The Fifth Circuit—conceding that admissibility of even the 1 item of only the 2 January 4, 1999 warning changes that it *did* mention, alone, would've changed the outcome—nevertheless held simply that any remedial warning changes, forced on the recalcitrant Respondent by the insuperable authority of the federal government, could not be considered as proof that the warning had previously been inadequate because the changes amounted to Fed.R.Ev., Rule 407 subsequent remedial measures inadmissible to prove fault, and with facile mindlessness brushed off the whole problem created by this Fifth-Circuit disagreement with the Eighth Circuit's decision in *O'Dell v. Hercules, Inc.*, 904 F.2d 1194, 1204 (8th Cir.1990), with the simplistic statement that "Such evidence of subsequent remedial measures cannot be considered in evaluating whether the 1997 warning was adequate," 283 F.3d at p. 270 n. 10—as if Respondent's belated and coerced 1999 and 2001 supplementations of its warning, with the truths Respondent had always known since the 1980s, had been the laudably spontaneous, self-motivated, social-conscious penance of a Little Goody Twoshoes that Rule 407 was designed to protect from forensic reprisal, instead of government-coerced reform-under-duress to which the Eighth Circuit, in *O'Dell*, *supra,* had held Rule 407 **does not extend.**

Circuit Conflict 2: The Fifth Circuit, in refusing to consider Respondent's warning changes **for any purpose at all,** as being Rule 407 subsequent remedial measures, 283 F.3d at p. 270 n.10, also thereby held them inadmissible for the expressly **permitted** purpose of **impeachment** of the adequacy of Respondent's pre-April 3, 1998 Lamisil warning, *i.e.,* impeachment of Respondent's allegations and summary judgment evidence that its pre-April 3, 1998 warning had

already been adequate and that its Lamisil is safe and innocuous—contravening Rule 407 itself and a plethora of its own and cases from other Circuits, *e.g., Kenney v. Southeastern Pennsylvania Transp. Authority,* 581 F.2d 351, 356 (3rd Cir.1978).

## ARGUMENT FOR GRANTING WRIT *RE* CIRCUIT CONFLICT

The Eighth Circuit ***held*** in *O'Dell v. Hercules, Inc.,* 904 F.2d 1194 (8th Cir. 1990):

> "[A]ppellants ... argue that the subsequent remedial activities and recommendations at issue were **forced** upon Hercules **by superior governmental authority** or were instituted by a third party, therefore **falling within a recognized exception to Fed.R.Evid. 407.** ***An exception to Rule 407 is recognized for evidence of remedial action mandated by superior governmental authority*** or undertaken by a third party ***because the policy goal of encouraging remediation would not necessarily be furthered by exclusion of such evidence.*** " 904 F.2d at p. 1204. (Boldface, italics, emphasis added.)

But the Fifth Circuit—**unimpressed** by the fact that drug companies including Respondent routinely defy for years FDA *requests* to change their warnings and never do change their warnings to advise of danger until *forced* to do so by the FDA (including, particularly, this Respondent; *see, Globetti v. Sandoz Pharmaceuticals Corp.* [Respondent's predecessor], No. CV98-TMP-2649-S, 2001 WL 419160 *1, *1-*2 (N.D.Ala.Mar.5, 2001)), **unimpressed** by the fact that the FDA had forced both the January 4, 1999 and May 8,

warning changes in *this* case on Respondent, **and so lost, confused and misguided** as not only to fly in the face of the Eighth Circuit's *O'Dell* but also to transgress **its own** strong *dictum* in *Rozier v. Ford Motor Co.*, 573 F.2d 1332, 1343 (5th Cir.1978) ("First, this 1971 document was ... not, in itself, a remedial measure taken ... [but] exclusion [under Rule 407] here is particularly inappropriate since the estimate was prepared not out of a sense of social responsibility but because the remedial measure was to be required in any event by a superior authority, the National Traffic Highway Safety Administration ... Our acceptance of Ford's [Rule] 407 argument would effectively 'turn the blade inward'.")—the Fifth Circuit contrarily held below, citing Rule 407, that the FDA-ordered remedial changes herein just "cannot be considered" **period,** 283 F.3d at p. 270 n. 10.

A serious crisis of policy for the United States is at stake here: A measure—of the extent to which the lengthening trail of corpses left in the last 2 decades by pharmaceutical manufacturers, particularly Swiss "pharmagiants" like Respondent (capitalized at $168 billion according to its own internet Web site), has caused them to be recognized not just nationally but worldwide as ruthless international poisoners for profit—is English master superspy-novelist John le Carré's latest best-selling exercise, *The Constant Gardener* (A.A. Knopf, 2001). Intended as a violent hatchet-job on the criminality of the Swiss pharmagiants, it merely scratches the surface with an exposé of skulduggery at only the pre-market-trials stage in third-world countries, leaving unscathed the worse lying to, concealment of vital information from, and manipulation, by pressure, intimidation and outright bribery, of government agencies charged with approval of marketing drugs, particularly the FDA.

The fact that criminal offenses at only the pre-market-drug-trials stage could attract the attention of commercial literary entrepreneurs like le Carré and his publishers, and the fact that their assessment—of the prevalence of, and of the extent of public concern over, pharmaceutical industry criminality—has been justified by sales of his book, signal that the delinquent behavior of drug manufacturers can no longer be dismissed as some rare, isolated or accidental freak but is so pervasive as to constitute a global scandal.

Nevertheless, sophisticated old Europe continues to seduce naïve young America: The FDA, instead of fulfilling its assignment as watchdog to protect U.S. citizens from the poisons from Switzerland and elsewhere that are selling like candy here in the American Happy Hunting Ground for so-called "legal" drug dealers (who do more harm to society than the recognized illegal ones but with complete immunity from criminal responsibility and with the barrier of a thousand legally sanctioned technical evasions against rarely imposed civil liability), has become a pharmaceutical companies' whorehouse embarrassingly obliged, after impotently making futile "requests" to drug companies to issue truthful and adequate warnings, to finally withdraw from the market more and more drugs that the FDA itself had been paid or tricked into approving—but only after the rising body count in victims killed or maimed by them has provoked outcry that can no longer be disregarded; *see, re:* a) **large number of drug withdrawals by the FDA after its approval of them,** *FEDERAL REGISTER INDEX, January-December 2001,* at p. 71, under "Food and Drug Administration," "Drugs," "Human Consumption," "NOTICES," "New drug applications—" "approval withdrawn" for 7 previously approved new drugs in 2001 alone; and *NBC Nightly News, Jan. 8, 2001 report,* "Is the FDA's Fast Track

Too Fast?" by R. Hagar; b) **pressure on and manipulation of FDA approval process,** *The New York Times* (National Ed.), Dec. 13, 2000, "Another Part of the Battle: Keeping a Drug in the Store," by J. Gerth and S.G. Stolberg, pp. A1 & A21, at A21, col. 1; and *Endocrine & Metabolic Drugs Advisory Committee to FDA, Meetings on Redux (Dexfenfluramine),* transcript downloadable from FDA Web site at www.fda.gov/ohrms/dockets/ac/redux.htm; c) **shenanigans practiced upon the FDA by pharmaceutical companies' falsification, underreporting and concealment of adverse events in reporting their pre-drug-approval trials,** *Journal of the American Medical Association,* January 24/31, 2001, "Completeness of Safety Reporting in Randomized Trials," by J.P. Ioannidis, M.D., and J. Lau, M.D.; 345 *New Eng. J. Med.* 825 (2001), "Sponsorship, Authorship, and Accountability," by F. Davidoff et al.; *35 DRUG INFO. J.* 269 (2001), "Is That Adverse Experience Really Expected? Guidelines for Interpreting and Formatting Adverse Experience Information in the United States," by Brown et al.; and *Office of the Inspector Gen., Dep't of Health & Human Servs.,* "Review of Food and Drug Administration's Handling of Adverse Event Reports," (Dec. 1999); and d) **payoffs to researchers and bribery of the FDA,** *TRIAL,* July 2001, at 16, "Undisclosed Industry Ties of Scientific Authors Undercut Credibility;" and *Lancet,* May 19, 2001, article by R. Horton stating that the FDA's Center for Drug Evaluation and Research ("CDER") "has become the servant of the [pharmaceutical] industry," and documenting the FDA's intimidation and exclusion of senior colleagues and suppression and ignoring of their opinion dissenting from drug approval, as well as the fact that the FDA's CDER receives funding from the pharmaceutical industry. (There was no issue below as

to whether Petitioner's case makes any pre-empted claim for fraud perpetrated on the FDA, as he asserts only state-law claims for inadequate warning, which are exempt from such federal pre-emption; *see, e.g., Motus v. Pfizer, Inc.,* 127 F.Supp.2d 1085, 1092 (C.D.Cal.2000), and *Globetti, supra,* at pp. *1-*2.)

But, while, in England, the penny has already dropped for a mere novelist like le Carré, the pathetically struggling morons and judicial geniuses alike, in the U.S., still just don't get it; *see,* relative to the hopelessly conflicting disarray of American jurisprudence in the drug-product-liability field—just as to admissibility of expert testimony in those cases—that is rewarding pharmagiants with more time to continue poisoning healthy people with impunity, *American Bar Association Journal,* January 2002, p. 22, "WHEN EXPERT TESTIMONY FAILS THE TEST, District Courts Disagree on What Defines Causation Evidence in Drug Disability Cases."

It is thus high time, as a matter of policy relative to a question of sufficient gravity, that the Supreme Court vindicate the nation's honor and integrity, and enhance its hygiene, by making a definitive statement in this area that will not only settle all barroom arguments but also **straighten out its conflicting subordinate Circuits.** For here is the Fifth Circuit marching off to war against the Eighth Circuit in the benighted delusion that it must not put a chill on some drug manufacturer's fictitiously imagined autogenic, voluntary incentive to remedy the cause of deaths and injuries it has perpetrated by hiding dangers of which it knew, when in reality no such incentive ever existed on which to put any chill because it was the government, and the government alone, that forced the remedy.

(Argument on the Circuit conflict created by failing to recognize admissibility of subsequent remedial measures for *impeachment,* as one of the exceptions provided by Rule 407 itself, is included in the Statement of Case *re* Circuit Conflict over F.R.Ev., Rule 407, pp. 3-11, *supra,* particularly under Circuit Conflict 2, at pp. 10-11.)

## STATEMENT OF CASE *RE* CIRCUIT COURT'S DEPARTURE FROM ACCEPTED & USUAL COURSE OF JUDICIAL PROCEEDINGS

Petitioner doesn't complain here of the "erroneous factual findings" for which certiorari is rarely if ever granted, for this was **summary** judgment, which is supposed to import that no such factual resolution needs to be made, not **trial** judgment in which weighing conflicting evidence to resolve fact issues is not only authorized but necessary. Rather Petitioner indicts the infirm and outlawed *method by* which the Fifth Circuit reached summary judgment in defying the principle that **any** competent **countervailing** evidence precludes summary judgment.

The Fifth Circuit's disposition to misrepresent Petitioner's position on both his evidence and argument first manifests itself at 283 F.3d p. 264 n. 4, stating that Petitioner "claims to have experienced these symptoms [jaundice, dark urine and pale stools] prior to the onset of his cholestatic hepatitis." Petitioner has **never** made that claim, and the Fifth Circuit's saying he did unjustifiably falsifies, trivializes and ridicules Petitioner's stance, as those are classic symptoms that one *already has* cholestatic hepatitis. Petitioner's only reference to his experience of those symptoms was that he passed dark urine and pale stools **before he became jaundiced** and that, because he had no idea that Lamisil had

caused those discolorations, he kept taking Lamisil for 4 more days until a Dr. Hines told him to stop because he had hepatitis and because Lamisil had caused it.

Again, the Fifth Circuit blithely set forth as though undisputed by Petitioner that the prescribing physician, Dr. Claiborne, told Petitioner about Lamisil's risk of liver problems and to return to him for blood testing after 6 weeks on Lamisil, 283 F.3d at p. 260, in the face not only of Petitioner's emphatic sworn denial thereof but also *Dr. Claiborne's* **own** sworn admission that he couldn't remember **anything** he told Petitioner besides **only** that Lamisil was supposed to be "safer than Nizoral," without any reason why or any statement of what any unsafety was.

But the foregoing were only the least of the misrepresentations of Petitioner's case by the Fifth Circuit. It is insultingly outrageous for a judicial tribunal to invent and put a stupid argument into the mouth of a litigant who never made that argument, for the purpose of using rejection of that argument as a reason for decision. Relative to the question at summary judgment whether Respondent's drug warning was adequate as a matter of law, the Fifth Circuit dishonestly wrote, "[Petitioner] Stahl argues that summary judgment on this issue was inappropriate because the adequacy of a warning is an issue of fact for the jury to decide," and immediately continued with, "This court has previously rejected the notion that a claim of inadequate warning always presents a jury issue," and "A 'mere allegation of inadequacy' is insufficient for a plaintiff to survive summary judgment on a failure-to-warn claim;" 283 F.3d at p. 264—as if Petitioner had ever absurdly contended that a party's allegation alone, without evidence, of drug-warning inadequacy *always* automatically guarantees trial on the merits, or had sat

back in fond and deluded reliance on the equally ridiculous converse that adequacy of a drug warning can **never** be the subject of summary judgment. But, first: "jury issue"—? This isn't a jury case—neither of the 2 opposing parties seasonably or ever asked for jury trial, a fact of which, *inter alia,* the Fifth Circuit maintained a determined ignorance—so Petitioner **never** made **any** such argument about a "**jury** issue." And, second: **Petitioner <u>never</u> made any of this argument at all, as to a bench-trial issue either, anyway.**

Instead, on the warning-inadequacy issue, Petitioner actually argued that **countervailing evidence, not** any misguided automatic legal rule of thumb, entitled him to trial on the merits, and he relied on (in addition to the FDA-mandated warning changes) competent, inescapably countervailing medical **evidence** that expressly denounced the warning as **in**adequate (as to admissibility of which there was **no** dispute), which frontally and flatly contradicted the District Court's summary conclusions that the Fifth Circuit affirmed. But both the District Court and the Fifth Circuit repeatedly refused to consider, account for or even mention the entirety of that medical evidence (except for the report of Dr. W.J. George, discussed *infra*, pp. 24-26). And the Fifth Circuit brushed aside Petitioner's importunate pleas to confront and deal with that evidence in a footnote in which the Fifth Circuit hid both the evidence itself and a multitude of its own follies behind the blanket façade of its statement that Petitioner's protest, that the Courts had "failed to consider the entirety of the record," is simply "without merit;" 283 F.3d at p. 260 n.1. But just *what* that "entirety of the record" that wasn't considered *was,* and *why* Petitioner's claim that it wasn't considered is without merit—the Fifth Circuit would not tell. If such treatment could suffice as

judicial opinion, disposition of whole appeals and their opposition could be encompassed within the single phrase that they are simply "without merit," so shortening jurisprudence as to cancel it entirely.

The following, then, is the competent countervailing evidence that Petitioner repeatedly shoved into the District Court's and the Fifth Circuit's faces without being able to get so much from either of them as an acknowledgment of its existence, much less an explanation of how a summary judgment at complete, diametric odds with it could be rendered:

*Re* Adequacy of Respondent's Liver Dysfunction & Cholestatic Hepatitis Warning

1) Petitioner's prescribing physician, Dr. Claiborne, testifying directly to the inadequacy of Respondent's Lamisil literature to inform him of even any risk itself, much less to inform him of the required **"actual level of** [any] **risk,"** said, "Of course, **we had no knowledge of: does [Lamisil] cause a liver disease(?)**; [and] when would be the best time [to start blood testing]? **None of those answers are available."** *Cholestatic hepatitis* **is** nothing else but a **liver disease,** yet the Fifth Circuit amazingly concluded, despite and with no reference to this testimony of his, that "Dr. Claiborne unequivocally testified that the Lamisil package insert's warning was clear, unambiguous and adequate to inform him of the risks of **cholestatic hepatitis** associated with prescribing Lamisil," 283 F.3d at p. 268, a *summary-judgment* conclusion that, in view of the evidence by which it is flagrantly contradicted, is worse than ridiculous, it is an outright falsification of testimony.

2) Petitioner's treating physician for Lamisil-induced hepatitis, Dr. Regenstein, asked if "there is something that you learned ... that you did not know from reading the [Lamisil] package insert," testified directly that the package insert failed to disclose—what even the Fifth Circuit conceded is required to be disclosed by Louisiana law—the **actual level of risk,** with his answer that "To me, it's the **unpredictable** and **severe nature** of the liver disease," for those characteristics are nothing else *but* **levels of the risk.** Also, asked if Respondent's Lamisil warning gave doctors information he also considers **essential,** as to the *incidence,* or rate of occurrence, of liver disease during Lamisil use, he flatly testified, "**No.**" The Fifth Circuit did not make bold to pervert these 2 testimonies by Dr. Regenstein, as it had done to Dr. Claiborne's testimony that the warning was inadequate to even reveal that Lamisil **causes** *any* liver disease, but, instead, held that there was no genuine issue as to the adequacy of the liver dysfunction/hepatitis warning, 283 F.3d at pp. 266-68, *by simply refusing to mention any of this testimony by Dr. Regenstein* **at all.**

*Re* Adequacy of Respondent's
Medical Monitoring Instruction

3) In its 2 Answers to Interrogatory 6, Respondent admitted it knew, *before* the 1998 prescription of Lamisil for Petitioner, that 17 patients who took Lamisil **for less than** the **6 weeks** of waiting for the Respondent-instructed 1st blood test, **died** of cholestatic hepatitis caused by Lamisil. The Fifth Circuit not only didn't even mislay this evidence as applicable to only whether Respondent should've warned that Lamisil kills, and not only wasn't persuaded that **it frontally contradicts the adequacy of Respondent's instruction to wait *more* than 6 weeks to begin**

**blood testing**—the Fifth Circuit didn't even grant this countervailing evidence "honorable mention" in *any* context **at all.**

4) Petitioner's prescribing physician, Dr. Claiborne, having testified as quoted *supra,* p. 19, that the blood-testing schedule instructed by Respondent's 1997 literature was inadequate to inform him when was "the best time" to start blood testing, testified further—even **before** Respondent implemented the FDA-ordered blood-testing-instruction changes—that he no longer believed in, followed or considered adequate (as he'd been duped into, as of prescription of Lamisil for Petitioner) Respondent's wait-till-7th-week instruction and that **he waits only 2-3 weeks to start testing blood** because **"if they are going to have any trouble, I would rather know about it ... earlier ... than six weeks."** The Fifth Circuit shied away from converting this segment of Dr. Claiborne's testimony into something new and different, as it had done to his testimony that the warning was inadequate to inform him that Lamisil **causes** *any* liver disease. Instead, the Fifth Circuit held that there was no genuine issue as to the adequacy of the medical-monitoring instruction, 283 F.3d at pp. 270-72, **by simply refusing to mention at all** that Dr. Claiborne had weighed in as heavily against adequacy of the blood-testing instruction as a doctor can: by refusing to obey it on the specific grounds that it didn't counsel blood testing early enough.

5) The Fifth Circuit also quietly banished under the rug, with the rest of the naughty medical indictments of Respondent's lies, Dr. Regenstein's testimony, germane to this blood-testing-schedule issue, that there is absolutely **no** medical monitoring scheme on which **he** would ever again prescribe Lamisil once he learned of its disastrous effects,

for he categorically swore in the most peremptory terms that **he would never again prescribe Lamisil *even with*** liver blood "tests **before** they [patients] were on it [Lamisil] and then ... **every two to four weeks afterwards.**"

*Re* Failure to Warn of Liver Failure and Death

3-A) Despite Respondent's confession, in its above-mentioned *(supra,* p. 20) Answers to Interrogatory 6, that it knew before prescription for Petitioner that Lamisil had caused liver failure and death, the Fifth Circuit held Respondent's Lamisil warning adequate without that distressing information, based on the subversion of logic that *a warning that cholestatic hepatitis has been "reported"* already imports a warning that Lamisil **causes liver failure** and **death**(!)just because those are merely **possible** complications of cholestatic hepatitis, 283 F.3d at p. 268. The screaming fallacy of that comatose reasoning is that those are possible complications of *only the very worst forms of hepatitis,* and that it is common knowledge not just among doctors—for the veriest dunce knows—that millions suffer all forms of viral, and toxic chemical, cholestatic hepatitis without developing liver failure or dying, such that merely telling *even a doctor* that "cholestatic hepatitis" has been "reported" does not tell him that **the actual level of risk** involved with **Lamisil** is **that it has caused** *liver failure* and *death.*

Any one, alone, of the foregoing 5 items was enough evidence of the inadequacy of Respondent's warning to obstruct summary judgment, even *without* the *additional* evidence thereof furnished by the FDA-ordered warning *changes.* Yet not even the Fifth Circuit's misrepresentation and burial of those items is the full extent of the mayhem wrought by the Fifth Circuit with the evidence,

which it would take many more pages than this to catalog. Nevertheless, the remoteness from the precincts of reason, as far as degrees of nonsense can be measured, of the Fifth Circuit's foregoing methods of concealing and turning evidence upside-down and backwards and of sabotaging logic, is easily outdone by the Fifth Circuit's fleering dishonesty in inserting into Petitioner's mouth and rejecting—with misplaced self-righteous intellectual condescension—foolishness that Petitioner never uttered. And all in order to affirm *summary judgment.*

Pulling such stunts is no way for a court to decide any case, much less an appeal from summary judgment, and when the Fifth Circuit did so it malfunctioned wildly out of control, "offered strange fire..., which [was] commanded them not" (Lev.10:1), and "departed [miles] from the accepted and orderly course of judicial proceedings ... [so] as to call for an exercise of [the Supreme] Court's supervisory power" within the meaning of Supreme Court Rules, Part III, Rule 10(a).

## ARGUMENT FOR GRANTING WRIT *RE* CIRCUIT COURT'S DEPARTURE FROM ACCEPTED & USUAL COURSE OF JUDICIAL PROCEEDINGS

(Argument on this point is included in the Statement of Case on this point, pp. 16-23, *supra.*)

## STATEMENT OF CASE *RE* CIRCUIT COURT DECISION IN CONFLICT WITH SUPREME COURT DECISIONS

Once the Fifth Circuit got caught dealing with **any** evidence that it hadn't changed or hidden, that Court failed to see that it was making of itself the embarrassing

spectacle of deeply engaging in the forbidden pursuit of ***resolving*** *evidentiary conflicts and genuine issues of material fact* in order to affirm *summary judgment.*

The **one piece of medical evidence** offered by Petitioner to controvert the adequacy of Respondent's blood-monitoring instruction (to wait till the 7th week on Lamisil to begin blood testing) **that the Fifth Circuit *did* deign to analyze** was the *report* of toxicologist/pharmacologist Dr. W.J. George (which the Fifth Circuit mischaracterized as his *"testimony"* with the words, "This assessment of Dr. George's testimony [*sic*]...," 283 F.3d at p. 271), expressing Dr. George's pre-FDA-changes opinion that, based on medical literature, blood monitoring of patients on Lamisil should begin—not in the 7th week on Lamisil as Respondent instructed, but—as early as 2 or 3 weeks following the initial dose of Lamisil, which would have **saved** both the liver of Petitioner, who didn't get sick until his 24th day on Lamisil, **and 17 lives.**

But, apparently confusing this case with an appeal from a trial rather than from the District Court's summary judgment, the Fifth Circuit yet again dropped the ball when it decided that this direct, specific evidence offered by Dr. George doesn't even count because it's too "vague," "tenuous," and "inadequate" to ***overcome*** Respondent's evidence and "create a genuine issue of material fact," 283 F.3d at p. 271, for the Fifth Circuit's so saying is its prohibited ***weighing*** of *evidence at summary judgment* in order to ***resolve evidentiary conflicts and issues of fact*** at that stage, specifically proscribed as error by the Supreme Court in *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986), and *Matsushita Electric Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587, 106 S.Ct.

1348, 89 L.Ed.2d 538 (1986).

Worse still, in this same respect, is the Fifth Circuit's additional reason for refusing to give Dr. George's opinion its countervailing effect, namely, that

> "Dr. George specifically cites only *one* pre-1998 [year of prescription for Petitioner] study, which details only *one* reported case where symptoms of liver dysfunction occurred as early as two to three weeks following initiation of treatment with terbinafine [the active agent in Lamisil]. Such equivocal and ill-supported testimony [*sic*, again] is simply insufficient to preclude summary judgment..." 283 F.3d at p. 272. (Italics in original, brackets added.)

The muddle-headed stupidity of the foregoing pronouncement is subdivisible thus: a) The Fifth Circuit completely forgot the evidence of Respondent's admission in its 2 Answers to Interrogatory 6 (mentioned *supra,* p. 20) that ***Respondent*** already knew **before 1998**—even if *Dr. George* didn't—that Lamisil had **killed *not*** "only *one"* person but ***17*** people in less than the 6 weeks Respondent instructed to wait to test blood, some in as little as 5 days or 2 weeks; b) Even if "only *one"* person *were* true, the Fifth Circuit's reasoning here is as if to say, Oh well, so what if their instruction was inadequate to prevent killing or injuring "only *one,"* the evidence is still uncontroverted that the instruction was adequate because what the heck is "only *one"* life(?), surely not enough to get in the way of summary judgment; c) Evidence does not become "equivocal and ill-supported" just because it emanates from "only *one"* source, and this type of inescapably **countervailing** evidence offered by non-mover, once it's admissible, as the Fifth Circuit

treated it, doesn't have to be "sufficient" or to *overcome* mover's evidence in order to create a fact issue at the summary-judgment stage—that's the business of a *trial,* all it has to do is ***oppose*** mover's evidence to defeat summary judgment by creating a fact issue, which anyone can see this evidence certainly does; and, finally, d) This counting of noses by the Fifth Circuit—in decrying the fact that Dr. George cited "only *one* pre-1998 study"—instead of weighing his evidence based on that one good study, would be error even at a *trial* (at which it *is* appropriate to *weigh* evidence, instead of counting, by adding or subtracting, evidentiary increments to arrive at a *numerical* preponderance of the evidence), but at summary judgment is sheer nonsense: "only *one"* piece of competent countervailing evidence—rejected by the Fifth Circuit as a cipher in the summary-judgment equation—is enough to beat all to chalk **any** summary judgment. Summary judgment must wither on the vine when faced with but a single "Nay" vote like the one here. Every two-bit lawyer already knows that's what summary judgment is all about whether the Supreme Court had ever said so or not.

But the Fifth Circuit used the foregoing discredited methods of resolving evidentiary conflicts at summary judgment in open rebellion against the dictates of the Supreme Court in *Anderson* and *Matsushita, supra.*

## ARGUMENT FOR GRANTING WRIT *RE* CIRCUIT COURT DECISION IN CONFLICT WITH SUPREME COURT DECISIONS

(Argument on this point is included in the Statement of Case on this point, pp. 23-26, *supra.)*

## CONCLUSION

A euphemistic description of the Fifth Circuit's work product below might charitably suggest that the Circuit wandered through the evidence in this case like the blindfolded characters at a pin-the-tail-on-the-donkey party (and missed), or that it was disadvantaged in having to view the evidence through eyeglasses coated with vaseline, while any honest attempt to explain the acrobatic gyrations and contortions engaged in by the Fifth Circuit to accomplish this disgracefully bungled botch-job could not avoid use of terms like "moronic," "dishonest" or "crazy." But even that is hardly the worst of it. For peeking out with naughty guiltiness from behind the enormous holes in the absurd *ostensible* reasoning of the Fifth Circuit herein is *quite another* rationale, the "guard stance" now being taken more and more by appellate courts to *resist* putting cases back into the system with remands to trial courts *in order to leave their dockets less crowded,* a policy responsible for the devising of so much atrocious nonsense as to render pointless anyway the having of such a judicial system for the cases that do remain, and a policy that is responsible in this case for the fact that **the Fifth Circuit now disagrees both with other Circuit Courts of Appeals as to F.R.Ev., Rule 407, and with the Supreme Court as to F.R.Civ.P., Rule 56(c),** not to mention that the Circuit's adherence to that policy has led it to mouth inanities, while stumbling and tripping with bewilderment and incomprehension over a few simple rules hardly constituting an obstacle course, that leave it in the position of having fronted for criminals who maim and kill with drugs for profit—incapable of imposing mere *civil* liability on documented *murderers.*

The Fifth Circuit's jokebook decision below, a formidably offensive combination of appalling dishonesty and incompetence, is just more of the exasperating goofiness that must often be manufactured in order to "AFFIRM DECISIONS," which has become the holy mantra now being sanctimoniously sung, chanted or intoned with ecclesiastical gravity, sickening monotony and disastrously crazy jurisprudential results by the robed priests of American justice—or only of American law. So it is that a recent study concluded that the death penalty should be abolished by the State of Illinois because the judicial system is now too flawed to serve as a basis for **any** definitive result, much less the ultimately drastic one (as reported in *The New York Times,* Sunday, April 21, 2002, Sec. 4, p. 2, Col. 1, "DEATH PENALTY REFORM," by Hubert B. Herring). The Fifth Circuit's decision in only *this* case is just *The Emperor's New Clothes* all over again.

No, the sky isn't falling. It already fell a long time ago—on the judicial system of which the U.S. Supreme Court is only the head. Petitioner isn't interested in fixing the broken judicial system of the United States or even in winning this case. He just isn't willing to take the Fifth Circuit's outrageous misrepresentation and mishandling of his evidence, and argument in this case lying down. Now that Petitioner has had his say, whether the Supreme Court grants certiorari becomes, for him, not even a secondary but only a tertiary issue, as (i) precarious health is necessarily Petitioner's overriding concern, dwarfing importance of (ii) his having his say and of (iii) his minuscule residual *academic* interest in what the Supreme Court does.

And, anyway, denial of certiorari will merely add but one more of thousands of testimonials to the Supreme

Court's celebratedly confessed disinterest in repairing the malfunction of other courts including its own subordinate Circuits, for, as Mr. Justice Frankfurter said in *Brown v. Allen,* writing separately *sub nom. Daniels v. Allen,* 344 U.S. 443, 491, 73 S.Ct. 437 (1953), "[T]he Court [is] complete master of its own docket. The governing consideration [is] authority to decline to review decisions which, right or wrong, do not present questions of sufficient gravity,"— and will add as well yet another testimonial to the truth, expressed by Mr. Justice Jackson concurring in the result in *Brown, supra,* with the immortal words, "We are not final because we are infallible, but we are infallible only because we are final," 344 U.S. at p. 540.

More than one kind of terrorist has long been unafraid to attack the United States. The FBI, CIA, INS, FDA and even the nation's judicial system can easily be walked all over, and this is become a known thing, for they have been. Before the "infallible" can rest on this case, they must "final[ly]" decide whether it raises "questions of sufficient gravity."

RESPECTFULLY SUBMITTED,

JOSEPH BRANDEIS STAHL
Attorney at Law, La. Bar No. 12383
U.S. Supreme Court Bar since 4/20/70
801 Whitney Bank Building
*228* St. Charles Avenue - Suite #801
New Orleans, LA 70130
(504) 525-4221
*Counsel of Record for/& Petitioner*

**APPENDIX A**
(5th CIRCUIT JUDGMENT & OPINION)

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

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No. 00-31440

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Filed
FEB 13 2002

JOSEPH B. STAHL

Plaintiff-Appellant

V.

NOVARTIS PHARMACEUTICALS CORP.

Defendant-Appellee

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Appeal from the United States District Court
for the Eastern District of Louisiana

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Before KING, Chief Judge, and DUHÉ and BENAVIDES, Circuit Judges.

KING, Chief Judge:

Plaintiff-Appellant Joseph B. Stahl appeals the district court's summary judgment in favor of Defendant-Appellee Novartis Pharmaceuticals Corporation on his claims under the Louisiana Products Liability Act. Stahl also appeals the district court's prior order dismissing his intentional tort claim. For the following reasons, we AFFIRM.

## I. FACTUAL AND PROCEDURAL BACKGROUND

Lamisil is a prescription drug manufactured by Defendant-Appellee Novartis Pharmaceuticals Corporation ("Novartis"). The drug is approved by the FDA for treatment of fungal infections in the toenails and fingernails. The package insert included with Lamisil during the time period relevant to this litigation contained warnings of a number of possible adverse reactions. The "WARNINGS" section of the insert stated: "Rare cases of symptomatic hepatobiliary dysfunction including cholestatic hepatitis have been reported. Treatment with Lamisil . . . Tablets should be discontinued if hepatobiliary dysfunction develops." The "PRECAUTIONS" section of the insert indicated that "[hlepatic function (hepatic enzyme) tests are recommended in patients administered Lamisil for more than six weeks or in those who develop unexplained nausea, anorexia, or fatigue." The "ADVERSE REACTIONS" section of the insert stated that "[r]are adverse events, based on worldwide experience with Lamisil . . . use include symptomatic hepatobiliary dysfunction, including cholestatic hepatitis

On April 3, 1998 Plaintiff-Appellant Joseph B. Stahl ("Stahl") was treated by Dr. Martin Claiborne, a dermatologist, for chronic fungal infection of the toenails. Dr. Claiborne prescribed Lamisil to treat Stahl's condition. Dr. Claiborne explained that he planned to treat Stahl's infection with Lamisil for twelve weeks, but prescribed only a six-week supply of the drug. Dr. Claiborne instructed Stahl to return to the doctor's office after the first six weeks of treatment for a liver (hepatic) function test, due to the risk of liver problems associated with use of Lamisil.

On April 27, 1998, twenty-four days after he began taking Lamisil, Stahl developed cholestatic hepatitis. He did not experience any nausea, anorexia, or fatigue prior to this time. His treating physicians have diagnosed his cholestatic hepatitis as drug-induced.

Stahl commenced the instant action against Novartis in district court on April 5, 1999. Stahl's initial complaint alleged negligent and intentional tort claims under the general tort liability provisions of Louisiana's Civil Code. See La. Civ. Code Ann. art. 2315 (West 1997 & Supp. 2002). In a July 14, 1999 order, the district court dismissed these claims on the ground that the Louisiana Products Liability Act ("LPLA") provides the exclusive remedy for products liability actions against manufacturers under Louisiana law. See La. Rev. Stat. Ann. § 9:2800.52 et seq. (West 1997). In that order, the district court gave Stahl leave to file an amended complaint. Stahl accordingly amended his complaint to allege two claims under the LPLA: that Lamisil is - unreasonably dangerous in composition," see id. § 9:2800. 54 (B) (1), and that Lamisil is "unreasonably dangerous because an adequate warning has not been provided," see id. § 9:2800.54 (B) (3).

After extensive discovery, Novartis filed a motion for summary judgment. On November 29, 2000 the district court granted this motion with respect to both of Stahl's LPLA claims, finding: (1) that Stahl had adduced no evidence apart from his own unsubstantiated allegations to support his "unreasonably dangerous in composition" claim, and (2) that the warnings contained in the Lamisil package insert were adequate as a matter of law.

Stahl appeals this summary judgment in favor of Novartis, arguing that the district court's conclusions were erroneous and that the district court improperly considered expert opinion in its summary judgment determination. Stahl further contends on appeal that the district court improperly dismissed the intentional tort claim raised in his original complaint because there is an "intentional acts" exception to the exclusive remedy provision-of the LPLA.[1] We will first address the viability of Stahl's intentional tort claim and then discuss the district court's summary judgment on his two claims under the LPLA. Initially, some background information on the LPLA is useful.

## II. THE LOUISIANA PRODUCTS LIABILITY ACT

To maintain a successful products liability action under the LPLA, a plaintiff must establish four elements: (1) that the defendant is a manufacturer of the product; (2) that the claimant's damage was proximately caused by a characteristic of the product; (3) that this characteristic made the product "unreasonably dangerous"; and (4) that the claimant's damage arose from a reasonably anticipated use of the product by the claimant or someone else. See La. Rev. Stat. Ann. § 9:2800.54 (A) (West 1997). A product is "unreasonably dangerous" under the LPLA if the product meets at least one of the following criteria:

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1 Stahl purports to raise nine claims of error in his brief. Most of these claims of error are encompassed within our review of the district court's dismissal order and subsequent summary judgment. Stahl's remaining "claims of error" appear to accuse the district court of mischaracterizing testimony in the record and of failing to consider the entirety of the record. Our own review of the record reveals that these claims are without merit.

> (1) The product is unreasonably dangerous in construction or composition as provided in R.S. 9:2800.55;
> (2) The product is unreasonably dangerous in design as provided in R.S. 9:2800.56;
> (3) The product is unreasonably dangerous because an adequate warning about the product has not been provided as provided in R.S. 9:2800.57; or
> (4) The product is unreasonably dangerous because it does not conform to an express warranty of the manufacturer about the product as provided in R.S. 9:2800.58.

Id. § 9:2800.54 (B). These statutory mechanisms for establishing that a product is unreasonably dangerous "are predicated on principles of strict liability, negligence, or warranty." Jefferson v. Lead Indus. Assoc., 930 F. Supp. 241, 245 (E.D. La. 1996). However, for causes of action arising after the effective date of the LPLA, negligence, strict liability, and breach of express warranty are not available as theories of recovery against a manufacturer, independent from the LPLA. See id.

To maintain a "construction or composition" defect claim under the LPLA, a plaintiff must establish that, at the time the product left the manufacturer's control, "the product deviated in a material way from the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the same manufacturer." La. Rev. Stat. Ann. § 9:2800.55 (West 1997). To maintain a failure-to-warn claim, a plaintiff must demonstrate that "the product possessed a characteristic that may cause damage and the manufacturer failed to use

reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product." Id. § 9:2800.57 (West 1997). Proving a design defect or a "construction or composition" defect is not a prerequisite to establishing a failure-to-warn claim. Even if a product is not defectively designed or constructed, a manufacturer "may .still have a duty to warn consumers about any characteristic of the product that unreasonably may cause damage." Grenier v. Med. Eng'g Corp., 243 F.3d 200, 205 (5th Cir. 2001).

## III. STAHL'S INTENTIONAL TORT CLAIM

The district court dismissed the claims in Stahl's original complaint, including his intentional tort claim, because these claims were not based on theories of liability recognized in the LPLA. We review the district court's dismissal of a claim de novo. Proctor & Gamble Co. v. Amway Co., 242 F.3d 539, 564 (5th Cir. 2001).

Because Stahl's cause of action accrued after September 1, 1988, the LPLA governs his claims. See Brown v. R.J. Reynolds Tobacco Co., 52 F.3d 524, 527 (5th Cir. 1995). As the district court correctly noted, the LPLA contains an exclusive remedy provision, stating that "[a] claimant may not recover from a manufacturer for damage caused by a product on the basis of any theory of liability that is not set forth in" the LPLA. La. Rev. Stat. Ann. § 9:2800.52 (West 1997). This provision limits a plaintiff's theories of recovery against a manufacturer of an allegedly defective product to those established by the LPLA. See, e.g., Jefferson, 930 F. Supp. at 244.

Stahl contends that the district court's dismissal of his intentional tort claim was nonetheless improper because there must be an "intentional acts" exception to the exclusive remedy provision of the LPLA. In support of this contention, Stahl cites a number of cases recognizing the existence of an intentional acts exception to the exclusive remedy provision of the Louisiana's Workers' Compensation Act (the "LWCA"). See, e.g., White v. Monsanto Co., 585 So.2d 1205, 1208 (La. 1991); Bazley v. Tortorich, 397 So.2d 475, 480 (La. 1981). Stahl reads this provision to suggest that "intentional tort is an exception to every exclusive remedy." We disagree.

Stahl is correct that the exclusive remedy provision of the LWCA contains an express exception for intentional acts. See La. Rev. Stat. Ann. § 23:1032 (B) (West 1998) ("Nothing in this Chapter shall affect the . . . liability, civil or criminal, resulting from an intentional act."). However, the fact that the LWCA contains such a provision does not imply that the LPLA's exclusive remedy provision is subject to a similar exception. There is no language in the LPLA indicating that its exclusive remedy provision does not preclude intentional tort claims, and both federal and Louisiana courts have read the Act's exclusive remedy provision to prevent plaintiffs from bringing intentional tort claims. See, e. g. , Grenier, 243 F. 3d at 203-06 (affirming the district court's dismissal of a fraud claim and other tort claims not among the exclusive theories of liability in the LPLA); Arabie v. R.J. Reynolds Tobacco Co., 96-0978 (La. App. 5 Cir. 6/30/97), 698 So.2d 423, 424-25 (granting summary judgment to defendants because plaintiffs' battery, fraud, and wrongful death claims were not among the exclusive theories of liability enumerated in the LPLA). Further, there is

no reason to read an intentional acts exception into the LPLA, as manufacturers are subject to suit under the Act for both intentional and unintentional acts.[2]

Because there is no "intentional acts" exception to the exclusive remedy provision of the LPLA, Stahl cannot bring intentional tort claims against Novartis under the Louisiana Civil Code for damages allegedly caused by Lamisil. Accordingly, the district court properly dismissed Stahl's intentional tort claim.

## IV. STAHL'S "UNREASONABLY DANGEROUS IN CONSTRUCTION OR COMPOSITION" CLAIM UNDER THE LPLA

The "unreasonably dangerous in construction or composition" provision of the LPLA provides a remedy for damages caused by a product that is defective due to a

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2 An "intentional acts" exception, while essential to the remedial scheme established in the LWCA, would be nonsensical in the context of the LPLA. The LWCA provides a remedy only for claims arising out of an "accident." See La. Rev. Stat. Ann. § 23:1031(A) (West 1998). That statute thus extends only to claims based on unintentional acts. Accordingly, the LWCA's exclusive remedy provision contains an exception allowing workers to bring tort claims based on intentional injuries because otherwise workers would have no legal remedy against their employers for such intentional tortious acts.

In contrast, the applicability of the LPLA does not turn on whether a manufacturer has acted "intentionally" in manufacturing a defective product. A claimant can bring an action under the LPLA based on conduct by a manufacturer that was either intentional or unintentional, presuming that the claim meets the statutory criteria outlined above. Thus, there is no need for a specific exception to the LPLA's exclusive remedy provision for "intentional acts," as intentional acts are encompassed within the LPLA's coverage provisions.

mistake in the manufacturing process. La. Rev. Stat. Ann. § 9:2800.55 (West 1997). As noted above, to prevail on a claim under this provision, the plaintiff must demonstrate that "at the time the product left its manufacturer's control, the product deviated in a material way from the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the same manufacturer." Id.

The district court granted summary judgment to Novartis on Stahl's construction or composition defect claim, finding that Stahl's "conclusory and unsubstantiated" assertions that Lamisil is unreasonably dangerous were insufficient to survive summary judgment. We review a district court's grant of summary judgment de novo, applying the same standard as the district court. See Rivers v. Cent. & S.W. Corp., 186 F.3d 681, 683 (5th Cir. 1999).

Stahl argues on appeal that the district court's summary judgment determination was erroneous because the district court misinterpreted Celotex Corp. v. Catrett, 477 U.S. 317 (1986). Stahl asserts that the court improperly placed the summary judgment burden on him, the non-moving party, without first requiring Novartis to come forward with documentary proof of the absence of a genuine issue of material fact regarding Stahl's claim. Stahl misreads both Rule 56 and the Celotex decision. Under Rule 56(c), summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56 (c). The moving party may meet its burden to demon-

strate the absence of a genuine issue of material fact by pointing out that the record contains no support for the non-moving party's claim. In this circumstance, if the non-moving party can point to nothing in the record supporting its claim, summary judgment is appropriate. As the Celotex Court explained, "Rule 56 (c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." 477 U.S. at 322. In such a situation there can be no genuine issue as to any material fact, since there has been a "complete failure of proof concerning an essential element of the nonmoving party's case." Id. at 323.

In the instant case, Novartis correctly argues that Stahl has provided no evidence raising a genuine issue of material fact as to whether Lamisil is unreasonably dangerous in construction or composition. While Stahl does provide some evidence that Lamisil's active ingredient can be dangerous to the liver, this evidence is not dispositive in a "construction or composition" claim under the LPLA. Therefore, summary judgment is appropriate because Stahl has not provided any evidence suggesting that the particular pills he received deviated in any way from the manufacturer's production standards or from the manufacturer's otherwise identical products.

## V. STAHL'S "INADEQUATE WARNING" CLAIMS UNDER THE LPLA

Stahl claims that Novartis failed to provide adequate

warnings regarding the dangers associated with Lamisil.[3] Stahl primarily contends that: 1) Novartis should have strengthened the wording of existing warnings to explicitly acknowledge the causal relationship between Lamisil use and liver dysfunction/cholestatic hepatitis; 2) Novartis should have added language to the package insert indicating that use of Lamisil can cause liver failure and death; and 3) Novartis should have recommended or mandated pre-administration blood testing and weekly or biweekly blood testing for all patients taking Lamisil or, at a minimum, should have recommended blood testing for patients who experienced early warning signs of liver damage, including jaundice, dark urine, and pale stools.[4]

To successfully maintain a failure-to-warn claim under the LPLA, a plaintiff must demonstrate that the product in question has a potentially damage-causing characteristic and that the manufacturer failed to use reasonable care to provide an adequate warning about this characteristic. See Grenier, 243 F.3d at 205 ("To prevail on her failure to warn claim, Grenier would need to show only that 'gel bleed' is a potentially damage-causing characteristic of MEC's

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3 Stahl also contends at various points in his brief that the limited warnings that Novartis provided were diluted by unfounded assurances of safety offered by its pharmaceutical sales representatives. However, there is no evidence in the record supporting this assertion. The only relevant evidence is Dr. Claiborne's testimony about his conversations with Novartis's drug representatives, and the record reveals that Dr. Claiborne testified unequivocally that the drug representatives informed him of the risks of Lamisil and never told him anything that was inconsistent with the label.

4 Stahl claims to have experienced these symptoms prior to the onset of his cholestatic hepatitis.

breast implants and that MEC failed to use reasonable care to provide an adequate warning."); see also La. Rev. Stat. Ann. § 9:2800.57 (A) (West 1997). To meet the first prong of this test, we have indicated that a plaintiff must provide evidence about the "cause, frequency, severity, or consequences" of the dangerous characteristic in question. Grenier, 243 F.3d at 205; see also Krummel v. Bombardier Corp., 206 F.3d 548, 552 (5th Cir. 2000) (finding that liability for failure-to-warn requires a plaintiff to provide evidence of the probability or risk of injury from the allegedly damaging characteristic of the product). However, in the instant case, neither party contests that Lamisil tablets have a potentially damage-causing characteristic (i.e., hepatoxicity). The parties only dispute whether Novartis used reasonable care to provide adequate warnings regarding this characteristic. Accordingly, we focus our attention on this inquiry.

The district court determined that the warnings contained in the Lamisil package insert were adequate as a matter of law. The court relied primarily on the testimony of Stahl's treating physician,. Dr. Claiborne, who indicated that the warnings contained in the Lamisil package insert were clear, unambiguous, and reasonably adequate to inform him of the risk of liver damage associated with the use of the drug. Stahl argues that summary judgment on this issue was inappropriate because the adequacy of a warning is an issue of fact for the jury to decide.

This court has previously rejected the notion that a claim of inadequate warning always presents a jury issue. See Anderson v. McNeilab, Inc., 831 F.2d 92, 93 (5th Cir. 1987) . A "mere allegation of inadequacy" is insufficient for

a plaintiff to survive summary judgment on a failure-to-warn claim. Id. Stahl must "go beyond the pleadings and designate specific facts in the record showing that there is a genuine issue for trial" to defeat summary judgment. Wallace v. Texas Tech Univ., 80 F.3d 1042, 1047 (5th Cir. 1996) .

Stahl further contends that the district court erred in basing its summary judgment determination on Dr. Claiborne's testimony. Stahl argues that because Dr. Claiborne is an expert in dermatology, not liver disease or the adequacy of drug warnings, the district court should not have considered his "expert" testimony regarding the adequacy of the warning without requiring a hearing under Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). Stahl further contends that, even if Dr. Claiborne's expertise in liver disease and the adequacy of drug warnings were established, such expert testimony cannot form the basis of a summary judgment determination.

We reject these contentions. When Dr. Claiborne testified as to the adequacy of the warning contained in the Lamisil package insert, he was not providing an expert opinion. While Dr. Claiborne was offered as an expert in the field of dermatology and fielded some questions in his deposition that called upon his expertise as a dermatologist, the portion of his testimony that was relevant to the district court's summary judgment determination involved his own understanding and perception of the warning label as Stahl's treating physician. In that capacity, Dr. Claiborne was testifying as to whether the Lamisil package insert made him aware of the risks involved in prescribing Lamisil at the time that he treated Stahl. This portion of Dr. Claiborne's

testimony does not constitute an expert assessment and is related to matters within the scope of Dr. Claiborne's personal knowledge.[5] It is appropriate for a district court to consider such testimony in evaluating a motion for summary judgment. See Fed. R. Civ. P. 56 (e).

We turn now to the substance of Stahl's inadequate warning claims. Louisiana applies the "learned intermediary doctrine" to products liability claims involving prescription drugs. Under this doctrine, a drug manufacturer discharges its duty to consumers by reasonably informing prescribing physicians of the dangers of harm from a drug. Anderson, 831 F.2d at 93. This court has acknowledged that

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5 This court has previously recognized that a treating physician does not necessarily testify in an expert capacity when he or she testifies as to the adequacy of the warning contained in a drug label. Indeed, no expertise outside the treating physician's field is required for such an assessment. See Mauldin v. Upjohn Co., 697 F.2d 644, 648 (5th Cir. 1983). As we reasoned in Mauldin:

> Upjohn insists that only an expert in the preparation or construction of medical product warning statements can testify properly as to the issue of adequacy. We cannot accept this argument, for it belies the essential purpose of the warning. Package inserts and PDR references are not written for medical experts schooled and skilled in the writing of warnings. They are written to inform fully and adequately the medical practitioner who is called upon . . . to prescribe the medication. The understanding and perception of [the prescribing physicians] is entirely relevant, for the sufficiency of the warning is dependent upon their reasonably anticipated comprehension.

Id. See also Zachary v. Dow Corning Corp., 884 F. Supp. 1061, 1065 (M.D. La. 1995) (noting that in the learned intermediary context, a manufacturer's duty to warn requires adequate warning of inherent dangers not within the knowledge of or obvious to the average learned intermediary).

there is a two-prong test governing inadequate-warning claims under the LPLA when the learned intermediary doctrine is applicable. First, the plaintiff must show that the defendant failed to warn (or inadequately warned) the physician of a risk associated with the product that was not otherwise known to the physician. Willett v. Baxter Int'l Inc., 929 F.2d 1094, 1098 (5th Cir. 1991). Second, the plaintiff must show that this failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff's injury. Id. Because we find that Stahl has failed to raise a genuine issue of material fact regarding the adequacy of the warnings contained in the Lamisil package insert, we reach only the first of these questions.

**The Adequacy of the Warnings Addressing Liver Dysfunction and Cholestatic Hepatitis**

Stahl's first inadequate warning claim is that the Lamisil package insert inadequately informed his treating physician of the risk of liver dysfunction and hepatitis associated with Lamisil use. While Stahl acknowledges that the "WARNINGS" section of the 1997 package insert specifically indicated that "[r]are cases of symptomatic hepatobiliary dysfunction including cholestatic hepatitis have been reported" and that "treatment with Lamisil . . . Tablets should be discontinued if hepatobiliary dysfunction develops," he contends that the wording of these warnings was not strong enough. According to Stahl, the warnings provided in the package insert were inadequate because they did not acknowledge the causal relationship between Lamisil use and liver dysfunction or cholestatic hepatitis.

Novartis maintains that the Lamisil insert fulfilled the company's duty to warn. Novartis points to a line of

cases decided under Louisiana law finding that a drug warning is adequate as a matter of law if it clearly and unambiguously notifies the prescribing physician of the particular adverse reaction that forms the basis of the plaintiff's complaint. See Bealer v. Hoffman-La Roche Inc., 729 F. Supp. 43, 44- 45 (E.D. La. 1990); Calhoun v. Hoffman-La Roche Inc., 98-2770, (La. App. 1 Cir. 2/18/00), 768 So.2d 57, 61-62. Indeed, one of those courts concluded that, if a warning label clearly and unambiguously states the particular ailment suffered by the plaintiff, summary judgment on a failure-to-warn claim is appropriate despite the prescribing physician's testimony that the warning did not adequately inform him of the risk involved. See Calhoun, 768 So.2d at 62 ("The Calhouns have not cited to us, nor have we found, any jurisprudential support for their contention that the test of whether a warning is adequate is subjective, based solely on the opinion of the prescribing physician.") Based on this line of authority, Novartis contends that the language in the insert indicating that "[r]are cases of symptomatic hepatobiliary dysfunction including cholestatic hepatitis have been reported" and that treatment "should be discontinued if hepatobiliary dysfunction develops," constitutes an adequate warning about the danger of liver dysfunction or cholestatic hepatitis as a matter of law because these portions of the warning mention Stahl's particular ailments.

Novartis is correct that in Calhoun and similar cases courts apparently interpreted Louisiana law to require summary judgment in favor of a drug manufacturer whenever the particular ailment suffered by the plaintiff is mentioned in the warnings section of the package insert, regardless of the prescribing physician's testimony about his or her

actual awareness and understanding of the risks involved. However, this suggestion that any clear and unambiguous reference to a particular adverse effect is sufficient to satisfy the manufacturer's duty to warn is inconsistent with this court's jurisprudence interpreting the LPLA. In applying the learned intermediary doctrine to an inadequate warning claim under the LPLA in Anderson, for example, we noted that "[u]nder Louisiana law, a drug manufacturer has discharged its duty to consumers of its prescription drugs when it has reasonably informed prescribing physicians of the dangers of harm from such a drug." Anderson, 831 F.2d at 93 (emphasis added). Thus, as our language in Anderson indicates, a mere reference to an adverse effect is not necessarily an "adequate warning" under the LPLA. The warning must contain language that is adequate to reasonably inform the recipient (i.e., the doctor in a learned intermediary case) about the nature of the danger involved. See also Restatement(Third) of Torts: Products Liability § 6 (d) (1997) (noting that a prescription drug or medical device "is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided") (emphasis added).

An alternate line of Louisiana authority suggests that a warning regarding a particular adverse drug reaction is adequate as a matter of law if the package insert clearly and unambiguously mentions the specific ailment suffered by the plaintiff AND the plaintiff's prescribing physician unequivocally testifies that the information provided in the warning was adequate to provide that physician with a reasonable understanding of the risks involved. Compare White v. Slidell. Mem'l Hosp. & Med. Ctr., No. 89-2691, 1990 WL 111447 (E.D. La. July 26, 1990) (finding sum-

mary judgment appropriate when the particular ailment suffered by the plaintiff was mentioned in the warning and the plaintiff's physicians', testified that they considered the manufacturer's warnings adequate); Mikell v. Hoffman-LaRoche, Inc., 94-0242, (La. App. 1 Cir. 12/22/94), 649 So.2d 75, 80 (affirming the trial court's summary judgment in favor of the defendant manufacturer when the particular ailment suffered by the plaintiff was specifically mentioned in the warning and the plaintiff's physicians' testified that they considered the manufacturer's warnings adequate); and Cobb v. Syntex Labs., Inc., 444 So.2d 203, 205-06 (La. Ct. App. 1984) (same) with Timm v. Upjohn Co., 624 F.2d 536, 539 (5th Cir. 1980) (finding that when a prescribing physician's testimony that a warning was adequate was not unequivocal, a jury is "entitled to weigh the conflicting statements made by [the prescribing physician] . . . along with all the other evidence presented in the case").

We find this second line of authority, represented by White, Mikell, and Cobb, to be a more persuasive reading of Louisiana law. Contrary to the holding of the Calhoun court, a prescription drug warning is not adequate as a matter of law simply because the warning label contains a clear and unambiguous reference to the adverse reaction suffered by the plaintiff. For summary adjudication of an inadequate warning claim to be appropriate, the plaintiff's prescribing physician must also unequivocally testify that the warning was adequate to inform him or her of the risks involved in prescribing the drug. The doctor's testimony provides added assurance that the language in the package insert was worded strongly enough to adequately inform him or her of the actual level of risk involved.

This reading of Louisiana law is consistent with the principles underlying the learned intermediary doctrine. Under Louisiana law, "[t]he obligation to the consumer is fulfilled when the prescribing or treating physician is informed of any potential side effects or risks from the drug's use so that they may intelligently decide on its use and advise the patient." McCarthy v. Danek Med., Inc., 65 F. Supp. 2d 410, 413 (E.D. La. 1999) (citing Mikell, 649 So.2d at 80). The premise underlying a failure-to-warn claim in the learned intermediary context is that the patient is claiming that the manufacturer failed to adequately warn the treating physician. The treating physician's knowledge is thus the focus of the inquiry. Accordingly, when a particular adverse effect is clearly and unambiguously mentioned in a warning label and the prescribing physician unequivocally states that he or she was adequately informed of that risk by the warning, the manufacturer has satisfied its duty to warn under the learned intermediary doctrine.

In the instant case, we agree with the district court that Dr. Claiborne unequivocally testified that the Lamisil package insert's warning was clear, unambiguous, and adequate to inform him of the risks of cholestatic hepatitis associated with prescribing Lamisil. Accordingly, the district court correctly determined that under Louisiana law, this warning is adequate as a matter of law. Summary judgment is appropriate on this claim.

**The Failure to Warn of Liver Failure and Death**

Stahl's second contention is that the Lamisil package insert was inadequate because it failed to warn prescribing physicians that liver failure and death could result from

from Lamisil use.[6] In considering this claim, the district court found that because Stahl had not yet suffered liver failure or death, he could not bring a failure-to-warn claim based on these dangers.[7] This logic is questionable. Because liver failure and death are widely recognized to be possible outcomes in a serious case of hepatitis (a condition that Stahl unquestionably suffered), it makes little sense to suggest that the plaintiff must wait until he dies to complain that the company failed to warn him of the risk of hepatitis-induced death. However, in the same vein, because liver failure and resulting death are widely recognized to be possible outcomes in a severe case of hepatitis, those risks are adequately addressed by the warnings already provided in the Lamisil insert.

Under Louisiana law, there is no duty to warn of obvious risks. See La. Rev. Stat. Ann. § 9:2800.57 (B). In the context of warnings addressed to a physician acting as learned intermediary, this court has interpreted this "obvious risk" exception to exclude any duty to warn of risks that are "within the knowledge of or obvious to the average learned intermediate." Willett, 929 F.2d at 1098 n.16.

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6 The two-part test described above, governing when a warning can be deemed "adequate as a matter of law" under the LPLA, is not applicable to this claim because the adverse effects that are the subject of this claim were not specifically mentioned in the warning label.

7 In reaching this holding, the district court relied on Grenier v. Med. Eng'g Corp., 99 F. Supp. 2d 759, 766 (W.D. La. 2000), aff'd, 243 F.3d 200 (5th Cir. 2001), which held that a claimant cannot seek to impose a duty to warn on a product manufacturer with respect to a damage not sustained.

Consequently, because any prescribing physician who is forewarned of a risk of systematic liver dysfunction and cholestatic hepatitis would find it obvious that there is an attendant possibility of liver failure and death, Novartis fulfilled its duty under the LPLA to warn physicians specifically of that possible outcome. Summary judgment is therefore appropriate.[8]

**The Adequacy of the Medical Monitoring Instructions**

Stahl's final failure-to-warn claim is that Novartis's recommended medical testing regime, indicating that "[h]epatic function (hepatic enzyme) tests are recommended in patients administered Lamisil for more than six weeks or in those who develop unexplained nausea, anorexia, or fatigue," was inadequate.[9] According to Stahl, Novartis should have recommended or mandated pre-administration

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8 This court has determined that "obviousness" can be appropriately evaluated as a matter of law in a summary judgment proceeding. See, e.g., Scallan v. Duriron, 11 F.3d 1249, 1252 (5th Cir. 1994) (determining that because "[t]he danger inherent in pumping chlorine through a hydraulic pump is obvious to an ordinary user of hydraulic pumps . . . . no genuine issue of material fact exist[ed] as to whether (the defendant] had a duty to warn"); see also Grenier, 99 F. Supp. 2d at 766 (determining in a summary judgment proceeding that "Defendants had no duty to warn against additional scarring that would result from additional surgery as scarring to some degree is an obvious consequence of surgery").

9 Stahl and Novartis dispute the exact meaning of this language. Novartis contends that this warning recommends that physicians perform blood testing on the subset of Lamisil patients that will be taking the drug for more than six weeks (i.e., those patients who take a twelve-week course of Lamisil to treat fungal infections of the toenails, rather than a six-week course to treat fungal infection of the fingernails).

blood testing and weekly or biweekly blood testing for all patients taking Lamisil or, at a minimum, should have recommended blood testing for patients who experienced early warning signs of liver damage, including jaundice, dark urine, and pale stools. Novartis contends that that this claim is not appropriately classified as a failure-to-warn claim because the blood testing recommendations contained in the package insert do not actually constitute "warnings." Novartis's position is that it is inappropriate to consider recommended medical monitoring schedules contained in a drug insert when evaluating the adequacy of a manufacturer's warnings. According to Novartis, such monitoring recommendations are mere suggestions - the actual determination of when and how to monitor the patient is left to the discretion of the treating physician.

We find Novartis's characterization of the recommended medical monitoring scheme unpersuasive. An inadequate warning claim under the LPLA can appropriately be based on alleged inadequacies in a recommended medical monitoring or testing regime. The LPLA provision defining an "adequate warning" encompasses "instructions" as well as "warnings." See La. Rev. Stat. Ann. § 9:2800.53 (9) (West 1997) (defining an "adequate warning" as a "warning or instruction that would lead an

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(footnote 9 continued)
Novartis maintains that this language does not purport to provide any particular instruction regarding the appropriate timing of this blood testing. Stahl, however, reads this recommendation to suggest that no blood testing is necessary until and unless a patient has been. taking Lamisil for more than six weeks. To the extent that this distinction makes any difference as a practical matter, for the purposes of reviewing Novartis's motion for summary judgment we shall construe the warning consistent with Stahl's interpretation.

ordinary reasonable user or handler of a product to contemplate the danger in using or handling the product and either to decline to use or handle the product or, if possible, to use or handle the product in such a manner as to avoid the damage for which the claim is made"); see also Restatement (Third) of Torts: Products Liability § 6(b) (1997) (noting that a prescription drug or medical device is defective if it "is not reasonably safe due to inadequate instructions or warnings") (emphasis added). Indeed, it is an accepted tenet of Louisiana products liability law that a manufacturer's duty to warn includes a duty to provide adequate instructions for safe use of a product. See Hines v. Remington Arms Co., Inc., 648 So. 2d 331, 337 (La. 1994). There appears to be no compelling reason to exempt recommended medical monitoring schemes — which are, in essence, instructions for safe use of prescription drugs — from a drug manufacturer's duty to warn. Louisiana courts have not specifically addressed whether a recommended medical monitoring program constitutes a "warning." However, many courts applying the law of other states have implicitly assumed that medical monitoring recommendations contained in package inserts are "warnings" by evaluating such recommendations (or the absence of such recommendations) in determining whether a drug manufacturer has fulfilled its duty to warn. See, e.g., Salmon v. Parke, Davis & Co., 520 F.2d 1359, 1362 (4th Cir. 1975) (applying North Carolina law) (finding that the plaintiff established a jury question precluding summary judgment by providing evidence that the blood studies recommended in a drug's warning label were inadequate); Fornoff v. Parke, Davis & Co., 434 N.E. 2d 793, 802 (Ill. App. 1982)(applying Illinois law) (indicating that the plaintiff's inadequate warning claim created a jury issue as to whether a drug "was so unpredictable in its rate

of absorption so as to require monitoring, and therefore a warning" to that effect); Formella v. Ciba-Geigy Corp., 300 N.W.2d 356, 359 (Mich. App. 1980) (applying Michigan law) (citing medical monitoring language in a warning label in support of the court's finding that a warning was adequate); Cooper v. Bowser, 610 S.W. 2d 825, 831-32 (Tex. Civ. App. 1980) (applying Texas law) (same).

In support of his inadequate warning claim, Stahl relies primarily on an expert report from Dr. William George, the Director of the Toxicology Center at the Tulane University School of Medicine.[10] In this report, Dr. George

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10 Stahl points to two other sources of support for his inadequate instruction claim. Initially, Stahl argues that Novartis's alteration of the Lamisil package insert in the years following his injury provides evidence that the 1997 version of the insert was inadequate. Specifically, he points out that the current version of the Lamisil package insert includes a warning that patients should undergo liver testing if they develop jaundice, dark urine, or pale stools. Such evidence of subsequent remedial measures cannot be considered in evaluating whether the 1997 warning was adequate. See Fed. R. Evid. 407 (indicating that evidence of subsequent remedial measures is not admissible to show a defect in a warning or instruction).

Stahl also attached to his memorandum opposing summary judgment a collection of lists of medical journal articles, paragraph-long summaries of medical journal articles (apparently obtained from an unidentified computerized database), and photocopied passages from medical journal articles purportedly discussing the relationship between terbinafine (the active ingredient in Lamisil) and liver problems. Stahl argues that these written materials demonstrate that Novartis had notice that earlier blood testing of Lamisil patients was necessary. While the district court does not appear to have addressed the admissibility of this evidence, we shall undertake this inquiry pursuant to our de novo review.

With the exception of two photocopied passages from medical journals where the title and date of the journal are identified in the photocopy, Stahl has presented insufficient indicia as to the authenticity of

opines (based on a literature review and review of Stahl's medical records) that Lamisil can cause symptomatic hepatobiliary dysfunction as early as two to three weeks following initiation of treatment. Dr. George concludes that hepatic function testing would be more likely to identify the onset of hepatoxicity in a more timely way if such testing was performed on patients taking Lamisil within three weeks of initial dosing.

At oral agument, Novartis argued that Dr. George's testimony was insufficient to create a genuine issue of material fact with respect to the adequacy of the medical monitoring instruction. Novartis also questioned the relevancy of Dr. George's testimony, pointing out that he is not an expert in the adequacy of warnings. We disagree with Novartis's suggestion that Dr. George's testimony is irrelevant because he is a toxicologist rather than an expert on warning labels. However, we agree with Novartis that Dr. George's testimony is insufficient to create a genuine issue of material fact with respect to the adequacy of the medical monitoring instructions.

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(footnote 10 continued)
these resources to satisfy the requirements of Rule 901 of the Federal Rules of Evidence. See Fed. R. Evid. 901 (a) ("The requirement of authentication or identification as a condition precedent to admissibility is satisfied by evidence sufficient to support a finding that the matter in question is what its proponent claims."). With respect to the two photocopied passages of medical journal articles, we find that the portions excerpted by Stahl are insufficient to create a genuine issue of material fact regarding the adequacy of the monitoring regime recommended in the Lamisil package insert, particularly in light of the fact that the excerpted passages present in full only the factual circumstances of the adverse incident(s) discussed in the articles. The portions of these articles analyzing and drawing implications from these adverse incidents are not included in full in the photocopies that Stahl has submitted.

The statutory definition of an "adequate warning" provides insight into the appropriate standard to govern inadequate instruction claims. As one commentator has aptly noted, the LPLA definition of an adequate warning contains two components, one component apparently addressing warnings, and one component apparently addressing instructions: "the warning must both lead the ordinary user or handler to contemplate the danger in using the product (the warning component) and to either use it safely (the instruction component) or decline to use it." See Thomas C. Galligan, Jr., The Louisiana Products Liability Act: Making Sense of it All, 49 La. L. Rev. 629, 677 (1989). Interpreting the statute in this manner, in order to prevail on an inadequate instruction claim for a prescription drug, a plaintiff must demonstrate that the instructions provided did not enable the treating physician to "use or handle the'[drug] . . . in such a manner as to avoid the damage for which the claim is made." La. Rev. Stat. Ann. § 9:2800.53 (9) (West 1997).

Dr. George's vague suggestion that "a number of reports in the literature indicate that hepatoxicity associated with terbinafine has occurred as early as weeks following initiation of treatment," coupled with his tenuous conclusion that testing "would be expected to be more effective" if conducted around two to three weeks following initiation of dosing, is inadequate to create a genuine issue of material fact as to whether the instructional language in the Lamisil package insert enabled treating physicians to use the drug safely. This assessment of Dr. George's testimony is bolstered by the fact that many of the reports upon which Dr. George relies were published after Stahl's injury in

1998.[11] Indeed, within the text of his report Dr. George specifically cites only one pre-1998 study, which details only one reported case where symptoms of liver dysfunction occurred as early as two to three weeks following initiation of treatment with terbinafine. Such equivocal and ill-supported testimony is simply insufficient to preclude summary Judgment on this inadequate warning claim.

## VI. CONCLUSION

For the foregoing reasons, we AFFIRM both the district court's summary judgment in favor of Novartis on Stahl's LPLA claims and that court's prior order dismissing Stahl's intentional tort claim.

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11 While a manufacturer has a duty to update warnings as new information about the risks of a product is discovered, see La. Rev. Stat. Ann. § 9:2800.57(C) (1997), a manufacturer's duty to warn a particular plaintiff is measured by the state of scientific and/or technical knowledge at the time the product left the manufacturer's control. See La Rev. Stat. Ann. § 9:2800.59(B) (1997) ("[A] manufacturer of a product shall not be liable for damage proximately caused by a characteristic of the product if the manufacturer proves that, at the time the product left his control, he did not know and, in light of then-existing reasonably available scientific and technological knowledge, could not have known of the characteristic that caused the damage or the danger of such characteristic.").

**APPENDIX B**
(5th CIRCUIT ORDER DENYING REHEARING)

IN THE UNITED STATES COUIRT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 00-31440

Filed MAR 15 2002

JOSEPH B STAHL

Plaintiff - Appellant

v .

NOVARTIS PHARMACEUTICALS CORPORATION

Defendant - Appellee

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Appeal from the United States District Court for the
Eastern District of Louisiana, New Orleans

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**ON PETITION FOR REHEARING**

Before KING, Chief Judge, and DUHÉ and BENAVIDES, Circuit Judges.

PER CURIAM:

IT IS ORDERED that the petition for rehearing is **denied.**

ENTERED
FOR THE COURT:

/s/ Carolyn Dineen King
United States Circuit Judge
REHG-2

**APPENDIX C**
(DISTRICT COURT DECISION)

**UNITED STATES DISTRICT COURT**
**EASTERN DISTRICT OF LOUISIANA**

Filed Nov 29 2000

**JOSEPH B. STAHL** **CIVIL ACTION**

**VERSUS** **NO. 99-1048**

**NOVARTIS PHARMACEAUTICALS CORPORATION** **SEC. "B"(3)**

**ORDER AND REASONS**

Before the Court is Defendant Novartis Pharmaceauticals Corporation's Motion for Summary Judgment (Rec. Doc. No. 31). The defendant, the manufacturer of the prescription drug Lamisil Tablets, seeks dismissal of this matter under the learned intermediary defense. Novartis claims that the warning was adequate and that the plaintiff cannot prove that but for the alleged inadequate warning that his treating physician would not have prescribed the Lamisil to him. In fact, Stahl's own treating physician who originally prescribed the tablets, Dr. Martin Claibome, III, testified in his deposition that the warning for Lamisil was clear, unambiguous and reasonably adequate to inform him of the risk of liver damage associated with the use of the drug and that he considered the warnings and risks when prescribing the drug. Stahl responds that the drug is unreasonably dangerous and that the warning is inadequate. The warning regarding "liver dysfunction," which means no more than working

DATE OF ENTRY
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unusually or improperly, does not address the risks of liver failure, death, and the need for a liver transplant. Dr, Claiborne testified that liver dysfunction does not tell him whether the drug causes liver disease. For the following reasons, the motion is **GRANTED.**

## BACKGROUND

Plaintiff Joseph B. Stahl began seeing a dermatologist, Dr. Emil Koretzky, in 1994 for chronic eczema. He received several tests during that time period regarding the skin treatment, including hepatic function tests, hepatitis tests, and an HIV test. The results were within normal parameters. On April 3, 1998, Stahl was examined by Dr. Claiborne for a chronic fungal infection of the toenails, which is called onychomycosis. Dr. Claiborne prescribed Lamisil to treat the onychomycosis. Dr. Claiborne explained that the treatment lasted twelve weeks, but that Stahl had to return after six weeks for a liver (hepatic) function test because there was a risk of liver problems associated with the use of Lamisil. Stahl suffered permanent liver damage, acute sympotomatic hepatobiliary dysfunction including cholestatic hepatitis, serious skin reactions, and changes in his ocular lenses and retinas. The liver and other medical problems surfaced in less than six weeks of taking the drug.

## LAW AND ANALYSIS

Summary Judgment is proper if the pleadings, depositions, interrogatory answers and admissions, together with any affidavits, show that there is no genuine issue as to any material fact and that the moving party is entitled to

judgment as a matter of law. Fed. R. Civ. P. 56(c); *see also Celotex Corp. v. Calrett,* 477 U.S. 317, 327, 106 S. Ct. 2548, 2554-55 (1986). A genuine issue exists if the evidernce would allow a reasonablejury to return a verdict for the nonmovant. *Anderson v. Liberty Lobby, Inc.,* 477 U,S, 242, 248, 106 S.Ct.2505,2510 (1986). Although the Court must consider the evidence with all reasonable inferences in the light most favorable to the non-moving party, the nonmovant must produce specific facts to demonstrate that a genuine issue exists for trial. *Webb* v. *Cardiothoracic Surgery Associates of North Texas,* 139 F.3d 532, 536 (5th Cir. 1998). The nonmovant must go beyond the pleadings and use affidavits, depositions, interrogatory responses, admissions, or other evidence to establish a genuine issue. *Id.* Accordingly, conclusory rebuttals of the pleadings are insufficient to avoid summary judgment. *Travelers Ins. Co. v. Liljeberg Enter., Inc.* 7 F.3d 1203, 1207 (5th Cir. 1993).

***Failure to Warn***

Although drugs and medications must be carefully administered and cautiously consumed, they are not so inherently dangerous that the manufacturer is held to guarantee that no harm will come to those who use those products. *DeBattista v. Argonaut-Southwest Insurance Co.,* 403 So.2d 26 (La. 1981). The manufacturer of a prescription drug has a duty to inform the prescribing physician of any potentially adverse side effects or risks from the drug's use. *Cobb v. Syntex Laboratories, Inc.,* 444 So.2d 203, 205 (La. App. 1st Cir. 1983). That obligation is satisfied if the manufacturer has informed the prescribing and treating physicians of the risks of harm from the drug so that they may intelligently decide on its use and advise the patient. *Id.* The

issue here is whether Novartis adequately informed the learned intermediary *(i.e.,* the treating physician) of the risk of injury actually suffered by the plaintiff.

A plaintiff must overcome two hurdles to succeed in a failure to warn case against a prescription manufacturer: (1) that the manufacturer failed to warn the treating physician of the dangers associated with the drug, *Willett v. Baxter Intl, Inc.,* 929 F.2d 1094, 1098 (5th Cir. 1991), and (2) but for the inadequate label, the treating physician would not have prescribed the drug to the plaintiff, *Id.* at 1099; *Wheat v. Fizer, Inc.,* 31 F.3d 340, 343 (5th Cir. 1994). The Court finds that Stahl cannot overcome either of these hurdles.

First, Novartis warned Stahl's treating physician, Dr. Claiborne, of the dangers associated with Lamisil. A warning on a prescription drug label is adequate as a matter of law if the label informs the doctor of the potential adverse reactions that the plaintiff claims that he suffered. *Calhoun v. Hoffman-LaRoche, Inc.,* 98-2770, p. 5 (La. App. 1st Cir. 2/18/2000); 768 So. 2d 57, 65 (affirming summary judgment against the plaintiff suffering from renal failure because the package insert for Toradol clearly and unambiguously warned that acute renal failure was a possible reaction to the use of Toradol); *Mikell v. Hoffman-Laroche, Inc.,* 94-0242 (La. App. 1st Cir. 12/22/94), 649 So.2d 75 (La. App. 1st Cir. 1994) (affirming summary judgment against a patient suffering inflammatory bowel disease because the PDR clearly stated that "inflammatory bDwel disease (including regional ileitis)" was a possible contraindication of Accutane usage); *Kinney v. Hutchinson,* 468 So. 2d 714, 718 (1985), *writ denied,* 472 So. 2d 35 (La. 1985) (affirming summary judgment against a bystander, shot by

an individual who was under the influence of the drug Preludin because the manufacturer's warning was sufficient to put the physician on notice that the drug carried the possibility of psychosis under normal dosage and of "confusion, assaultiveness, hallucinations, panic states" with overdosages); and *Cobb,* 444 So. 2d at 206 (affirming summary judgment against a plaintiff suffering a stroke after taking contraceptives because the warning, which advised of an increased risk of suffering a stroke or other circulatory ailment, was deemed adequate).

In the present case, Stahl's complaint alleges that the Lamisil tablets have caused "severe, extensive and permanent wreckage to his liver rendering him desperately and dangerously ill with acute symptomatic hepatobiliary dysfunction including cholestatic hepatitis, caused [him] to suffer serious skin reactions, caused changes in the ocular lenses and retinas . . ., and caused other disorders." Consistent with the liver damage allegation, at least three physicians have diagnosed Stahl as having cholestatic hepatitis. For example, Dr. Luis Balart diagnosed the plaintiff as suffering from cholestatic hepatitis secondary to antifungal agent. Dr. Edward J. Martin, Ill's pathology report opines: "While the findings here of acute cholestatic hepatitis are compatible with drug induced injury, other hepatitic processes cannot be completely ruled out." Dr. Salima Haque concluded that "[s]evere cholestasis is present predominantly around the central veins associated with mild hepatocellar necrosis and generalized cellular disarray." He further explained that the features present "are suggestive of drug induced hepatic injury, mixed hepatocellular and cholestatic type with paucity of bile ducts."

The Court finds that Novartis warned of all conditions of which Stahl complains and that his treating physician understood those warnings. Stahl's treating physician, Dr. Claiborne, testified that he read and understood the Lamisil package inserts and that he kept himself apprised of new information through peer review journals and medical meetings. The warnings, precautions, and adverse reactions provide in pertinent part as follows:

> **WARNINGS** Rare cases of symptomatic hepatobiliary dysfunction including cholestatic hepatitis have been reported.... There have been isolated reports of serious skin reactions (e.g., Stevens-Johnson Syndrome and toxic epidermal necrolysis) .... **PRECAUTIONS** Changes in the ocular lens and retina have been reported following the use of Lamisil (terbinafine hydrochloride tablets) Tablets in controlled trials. The clinical significance of these changes is unknown. Hepatic function (hepatic enzyme) tests are recommended in patients administered Larnisil for more than six weeks .... Transient decreases in absolute lymphocyte counts (ALC) have been observed in controlled clinical trials.... The clinical significance of this observation is unknown. However, in patients with known or suspected immunodeficiency, physicians should consider monitoring complete blood counts in individuals using Lamisil for greater than six weeks. Isolated cases of severe neutroperia have been reported. . . . **ADVERSE REACTIONS** The adverse events reported [in placebo-controlled trials] encompass gastrointestinal symptoms (including diarrhea, dyspepsia, and abdominal pain), liver

> test abnormalities, rashes, urticaria, pruritus, and taste disturbances. In general, the adverse events were mild, transient, and did not lead to discontinuation from study participation.

Dr. Claiborne testified that he knew that the use of Lamisil involved a risk of liver pathology, hepatobiliary dysfunction, hepatitis, and serious skin reactions. Dr. Claiborne admitted under oath that the warnings do not qualify when during course of treatment that the potential problems would occ Similarly, he acknowledged that he understood that hepotobiliary dysfunction and skin problems could occur at any point during the course of treatment. Further, Dr. Claiborne testified that he told Stahl that Lamisil "could cause some liver abnormalities and that's why [they] would be checking for liver enzymes." Finally, contrary to Stahl's assertions that Lamisil would not be prescribed if it was known that it did not cure patients, Dr. Claiborne testified that he knew that Lamisil did not have a 100% cure rate. He further testified that he prescribed it because it had a better safety profile than the other drugs used to treat onychomycosis. Moreover, Dr. Claiborne admitted that he still would have prescribed Lamisil to Stahl even if the label had included the monitoring demanded by Stahl and that he continues to prescribe Lamisil to his patients. Although he currently tests his patients after the fourth week, because of his experience with Stahl, none of his other patients have experienced complications from their use of Lamisil.

Even though Dr. Claiborne said that the warnings did not give him specific knowledge of when would be the best time to conduct testing for liver problems, the warning

unambiguously advised of the risks of the liver and skin conditions that Stahl's complaint alleges that he suffered. In *Theriot v. Danek Medical, Inc.*, 168 F.3d 253, 256 (5th Cir. 1999), the Fifth Circuit affirmed summary judgment for a manufacturer where the doctor testified that he was fully apprised of the potential risks of the product despite the plaintiff's arguments that because the manufacturer did not adequately test the product, it could not have properly inform the doctor of the risks. The court explained that the manufacturer only had an obligation to inform Dr. Billings of the risks of pedicle screws and that there was no basis in the Louisiana Product Liability Act or case law for the plaintiff's argument. The *Theriot* court found that the district court did not err in dismissing the case. Because the warnings here advised Dr. Claiborne of the risks actually suffered by this plaintiff, the Court finds that the hypotheticals posed to Dr. Claiborne in his deposition concerning weekly and bi-weekly testing are irrelevant.

Further, this Court is unpersuaded by Stahl's complaints that the warnings did not warn of death, liver failure and the need for transplant. Stahl has not suffered any of those injuries and is, therefore, precluded from imposing a duty to warn regarding those injuries not suffered. Stahl has been diagnosed with a liver disease, cholestatic hepatitis, not liver failure.[1] In *Grenier v. Medical Eng'g Corp.*, 99 F.Supp.

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1 While the medical dictionary defines *cholestatic hepatitis* as a condition in which an "inflammation of the liver" causes a "stoppage or suppression of the flow of bile," it does not classify the condition as complete "liver failure." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY, pp. 318,753 (28th ed. 1994). A *malfunction* of the liver is not a *failure* of the liver. Further, if this condition is deemed to be liver failure as alleged by the plaintiff, the warning clearly references the risk of cholestatic hepatitis.

2d 759, 766 (W.D. La. 2000), the court concluded that a "claimant cannot seek to impose a duty to warn on a manufacturer of damage not sustained." In that case, although the plaintiffs amended complaint cited "rupture of the breast implant" as an injury she sustained, the court noted that subsequent filings confirmed that she had not sustained that particular injury. The *Grenier* court rejected the plaintiff's attempt to impose a duty to warn regarding an injury not actually suffered by her. So, too, this Court's review of Stahl's failure to warn claim is limited to the injuries actually sustained by him.

Thus, the Court finds that the warnings, as issued by Novartis, were sufficient to put the treating physician, Dr. Claiborne, on notice that Lamisil carried the possibility of symptomatic hepatobiliary dysfunction (including cholestatic hepatitis), serious skin reactions, changes in the ocular lens and retina, and taste disturbance. The warnings also notified him of several adverse reactions including malaise, fatigue, vomiting, arthralgia, myalgia, and hair loss. The information provided reflected the state of medical knowledge at the time the warnings were issued. Monitoring for those complications was within the discretion and province of the treating physician once he was informed of the potential risks. The Court finds that, as in *Theriot*, the warnings adequately informed the treating physician of any potential side effects or risks from the drug's use so that he could intelligently decide on its use and advise Stahl. Dr. Claibornes testimony convinces this Court that he had adequate information to weigh the risks versus the utility of Lamisil and that he made an informed medical decision to prescribe Lamisil for Stahl.

Second, the Court finds that Stahl cannot survive the "but for" test. Dr. Claiborne would have prescribed Lamisil for Stahl any way. Dr. Claiborne testified that Lamisil was more effective than the other drugs used to treat toenail fungus. He explained:

> Lamisil is generally considered to be the best pill. There are four pills used to treat - actually five pills used to treat fungus of the toenails. The original pill, Griseofulvin, it has been out 40 years. It has approximately 25- to 30-percent cure rate. The next pill would be Nizoral. Nizoral has about a 35- to 40-percent cure rate but can be associated with a drug-induced hepatitis, and for that reason is not used very much any more. The next three pilis involve Diflucan ... which is normally used to treat yeast infection of the toenails.... There are two pills used to treat fungus of the toenails, one of them is Sporonox. . . . and the other is Lamisil. Sporonox is fungistatic, meaning it prevents the fungus from reproducing.... Lamisil is the only pill that is fungicidal. Sporonox is quoted to have a cure rate of 60 to 70 percent. [Lamisil. is] fungicidal and at this point in time is generally considered the preferred treatment for fungus of the toenails by most dermatologists.

Additionally, Dr. Claiborne noted that Lamisil is "generally considered by most people to be the most effective and the least dangerous" drug because it has a higher cure rate, because it is fungicidal instead of fungistatic, and because it does not have the drug interaction problems associated with other medicines. Stahl did not have a history of liver problems, and the liver function tests conducted on Stahl a

few years earlier in connection with his skin treatments were within normal parameters. Moreover, Dr. Claiborne is a long-time subscriber of Lamisil who has not experienced any complications or adverse reactions in any patient other than Stahl. Dr. Claiborne noted that regardless of the recommendations contained in the PDR based upon the incidence of certain complications in clinical and post marketing trials, a physician always has the discretion to use his own clinical judgment and employ whatever monitoring is appropriate under the circumstances of an individual patient's case. The Court finds that the evidence does not support that but for the inadequate label, the treating physician would not have prescribed the drug to the plaintiff. To the contrary, Dr. Claiborne's satisfaction with the drug, its success rate, its fungicidal composition, its medical profile, and the absence of a liver dysfunction history in Stahl indicate that Dr. Claiborne's decision to prescribe Lamisil for Stahl would not have been altered. Novartis' obligation under the learned intermediary doctrine therefore was satisfied.

***Unreasonably Dangerous***

Stahl claims that Lamisil is unreasonably dangerous in composition. However, he does not provide any summary judgment proof to support this claim. In order to prove this theory of liability under La. R.S. § 9:2800.55, he must establish that the drug "deviated in a material way from the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the same manufacturer." Stahl's conclusory and unsubstantiated rebuttal that the drug is unreasonably dangerous is insufficient to avoid the summary judgment

requested by the defendant. *See Little v. Liquid Air Corp.*, 37 F. 3d 1069,1075 (5th Cir. 1994) *(en banc); see also Michaels v. Avitech, Inc.*, 202 F. 3d 746, 754-55 (5th Cir, 2000) (inferences were insufficient to avoid summary judgment); *Wilson Industries, Inc. v. Aviva America, Inc.*, 185 F.3d 492, 494 (5th Cir. 1999) (explaining that the non-movant cannot satisfy his summary judgment burden with conclusory allegations, unsubstantiated assertions, or only a scintilla of evidence); *Krim v. BancTexas Group,* Inc., 989 F.2d 1435, 1449 (5th Cir. 1993) (summary judgment is appropriate if "non-moving party rests merely upon conclusory allegations, improbable inferences, and unsupported speculation"). Dismissal of this claim is therefore appropriate. Accordingly,

**IT IS ORDERED** that Defendant Novartis Pharmaceauticals Corporation's Motion for Summary Judgment (Rec. Doc. No. 31) is **GRANTED.**

New Orleans, Louisiana, this 29th day of November, 2000.

/s/ Ivan L.R. Lemelle
IVAN L.R. LEMELLE
UNITED STATES DISTRICT JUDGE

**UNITED STATES DISTRICT COURT**
**EASTERN DISTRICT OF LOUISIANA**

Filed Nov 29 2000

**JOSEPH B. STAHL** **CIVIL ACTION**

**VERSUS** **NO. 99-1048**

**NOVARTIS PHARMACEAUTICALS CORPORATION** **SEC. "B"(3)**

**FINAL JUDGMENT**

The Court granted the defendant's Motion for summary Judgment on November 29, 2000 after finding that summary judgment was appropriate. Entry of a final judgment regarding the dismissal of the defendant from this litigation is proper because the November order dismissed all claims against the defendant. Accordingly, for the reasons provided in this Court's November 29, 2000 opinion,

**IT IS ORDERED, ADJUDGED, AND DECREED** that there be Judgment in **favor** of Defendant Novartis Pharmaceauticals Corporation and against Plaintiff Joseph B. Stahl, dismissing with prejudice his claims against the defendant, each party to bear its own costs.

New Orleans, Louisiana, this 29th day of November, 2000.

/s/ Ivan L.R. Lemelle
IVAN L.R. LEMELLE
UNITED STATES DISTRICT JUDGE

DATE 0F ENTRY NOV 3 0 2000

Supreme Court, U.S.
FILED
JUL 18 2002
OFFICE OF THE CLERK

No. 01-1835

IN THE

# Supreme Court of the United States

JOSEPH BRANDEIS STAHL,

*Petitioner,*

*v.*

NOVARTIS PHARMACEUTICALS CORPORATION,

*Respondent.*

**ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT**

## BRIEF IN OPPOSITION

JOY GOLDBERG BRAUN
*Counsel of Record*
ERIC R. NOWAK
SESSIONS, FISHMAN, & NATHAN LLP
*Attorneys for Respondent*
201 St. Charles Avenue
35th Floor
New Orleans, LA 70170
(504) 582-1500

175049

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

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## STATEMENT PURSUANT TO RULE 29.6

Respondent, Novartis Pharmaceuticals Corporation, is an indirect, wholly-owned subsidiary of Novartis AG. Novartis Pharmaceuticals Corporation's parent companies are:

(1) Novartis Finance Corporation;

(2) Novartis Corporation;

(3) Novartis Holding AG, a Swiss company; and

(4) Novartis AG, a Swiss company, publicly traded on the New York Stock Exchange (symbol: NVS).

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## STATEMENT OF THE CASE

On April 5, 1999, Petitioner filed suit against Novartis Pharmaceuticals Corporation ("Novartis"), the manufacturer of the prescription drug Lamisil Tablets® ("Lamisil®"). Petitioner alleged that Lamisil® damaged his liver by causing symptomatic hepatobiliary dysfunction, including cholestatic hepatitis. As Petitioner admitted and as the courts below determined, however, the labeling for Lamisil® at the time Petitioner was prescribed Lamisil® contained warnings concerning the complications allegedly suffered by Petitioner.[1]

The district court granted summary judgment in favor of Novartis after finding the Lamisil® label adequate as a matter of law pursuant to Louisiana's "learned intermediary doctrine." Under this doctrine, a prescription drug manufacturer does not have the obligation to directly warn patients who use a drug of its potential risks. Rather, the manufacturer has a duty to inform the prescribing physician — the learned intermediary — of the potential side effects and risks that arise from the drug's use. *Zachary v. Dow Corning Corp.*, 884 F. Supp. 1061, 1065 (M.D. La. 1995); *Mikell v. Hoffman-LaRoche, Inc.*, 649 So. 2d 75, 79 (La. App. 1 Cir. 1994), citing *Cobb v. Syntex Lab.*, 444 So. 2d 203, 205 (La. App. 1 Cir. 1983).

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1. As reproduced in the Fifth Circuit's opinion below, the labeling for Lamisil® contained the following language:

> WARNINGS
>
> Rare cases of *symptomatic hepatobiliary dysfunction including cholestatic hepatitis* have been reported. Treatment with Lamisil (terbinafine hydrochloride tablets) *Tablets should be discontinued if hepatobiliary dysfunction develops (see PRECAUTIONS).*

*See* Pet. App. at A15 and A34.

Petitioner appealed the district court's ruling to the Fifth Circuit. On *de novo* review, the Fifth Circuit affirmed the district court's ruling, finding that there was no material issue of disputed fact, and that the Lamisil® label was adequate as a matter of law. *Stahl v. Novartis Pharmaceuticals Corp.*, 283 F.3d 254 (5th Cir. 2002).

## REASONS FOR DENYING THE WRIT

The decisions of the courts below reflect a straightforward application of Louisiana law to the undisputed facts of this case. Notwithstanding Petitioner's contention that a footnote in the Fifth Circuit's opinion regarding the admissibility of subsequent changes to the Lamisil® label conflicts with the Eighth Circuit's treatment of a similar issue more than a decade ago in *O'Dell v. Hercules, Inc.*, 904 F.2d 1194 (8th Cir. 1990), the Fifth Circuit's decision in fact creates no circuit conflict, and Petitioner's request for writ of certiorari should be denied.

### I. Misstatements of Fact

The Petition contains numerous misstatements, most of which are not relevant to Petitioner's arguments. Pursuant to the requirements of Supreme Court Rule 15.2, however, Novartis identifies particular misstatements in the Petition that could conceivably "bear on what issues properly would be before the Court if certiorari were granted." Sup. Ct. Rule 15.2.

- Petitioner's bare contention that subsequent changes to the Lamisil® label were "involuntary" (Pet. at 9) is unsupported by the record (and wrong).

- Petitioner's allegations regarding Lamisil® advertising (Pet. at 4) are unsupported by the record (and incorrect).

- The medical records and testimony of Petitioner's treating physicians do not support Petitioner's allegation that he was "almost killed" as a result of his injuries (Pet. at 4).

- The evidence in the record does not support Petitioner's incorrect allegation that the Lamisil® label, warnings, and literature from Novartis established a medical monitoring regimen that mandated a "delay in commencement" of liver–function tests "until the 7th week" of taking Lamisil® (Pet. at 4, 8, 20). Similarly, Petitioner cannot point to any evidence in the record to support his allegation that patients taking Lamisil® should undergo "pre-treatment, and earlier than 7th-week liver–function testing" (Pet. at 8).

- There is no evidence to support Petitioner's wrong and inflammatory statements that 17 people have been "killed" by Lamisil® (Pet. at 4, 8, 20), or that Novartis "lied," "concealed" information, and "downplayed" levels of risk associated with Lamisil® (Pet. at 5-6).

- The record contains no support for Petitioner's incorrect statement that Lamisil® is "inherently hepatotoxic" (Pet. at 8).

- Petitioner misstates the report of Dr. George (Pet. at 8). The record reflects that Dr. George never rendered an opinion that the labeling for Lamisil® was inadequate, nor did he propose a mandatory testing regimen for the millions of individuals who are prescribed Lamisil®.

- Petitioner misstates the testimony of Dr. Regenstein (Pet. at 20-21). The record reflects that Dr. Regenstein, the Petitioner's treating heptologist and not the learned intermediary in this case, had knowledge of the risk of hepatobiliary dysfunction and its unpredictable nature. Furthermore, Dr. Regenstein claimed no expertise in drug product warnings.

- Petitioner misstates the Lamisil® label by alleging that the term "mild" in the label was used to describe adverse events generally (Pet. at 9).

- There is no legal support for Petitioner's claim that it is "axiomatic" and "uniformly held" that a subsequent change in a prescription label establishes that a "pre-change warning was inadequate" (Pet. at 9). Even the 35-year old California state court opinion that Petitioner cites for this proposition does not support his argument. *See Love v. Wolfe*, 249 Cal. App. 2d 822, 831 (Cal. App. 3d Dist. 1967) (holding only that there was no prejudicial error created by admitting subsequent label because subsequent label could have been admitted for purpose of impeaching specific testimony of defendant's witnesses, and because defendant failed to seek limiting instruction at time evidence was introduced).

- Petitioner misidentifies Respondent as a Swiss Corporation. Novartis Pharmaceuticals Corporation is a Delaware Corporation with its principal place of business in the State of New Jersey.

## II. The Decisions Below Reflect An Application of Settled Law to Undisputed Facts.

The decisions of the district court and Fifth Circuit in this case reflect an uncontroversial application of Louisiana law to undisputed facts. State and federal courts uniformly have held that a warning is adequate as a matter of Louisiana law if it informs the doctor of the potential adverse reactions that are the basis of the lawsuit. *Anderson v. McNeilab, Inc.*, 831 F.2d 92, 93 (5th Cir. 1987); *Bealer v. Hoffman-La Roche*, 729 F. Supp. 43, 44-45 (E.D. La. 1990); *Calhoun v. Hoffman-La Roche, Inc.*, 2000 WL 202067, at *5 (La. App. 1 Cir. 2000); *Kinney v. Hutchinson*, 468 So. 2d 714, 718 (La. App. 5 Cir. 1985); *Cobb v. Syntex Lab.*, 444 So. 2d 203, 206 (La. App. 1 Cir. 1983). The courts below applied this rule of law to the undisputed facts in the record concerning: (1) the content of the Lamisil® product information; (2) the Petitioner's alleged injury; and (3) the treating physician's knowledge of the risks that are at issue.

None of Petitioner's arguments — either below or in his Petition for Writ of Certiorari — creates or identifies a disputed fact that is material to this analysis under the learned intermediary doctrine. The Fifth Circuit correctly determined that the Lamisil® product information was adequate as a matter of law and affirmed entry of summary judgment in favor of Novartis.[2] Moreover, as the opinions of the district

2. Previous decisions by federal and state courts applying Louisiana law demonstrate the straightforward nature of the analysis in this case. *See, e.g., Wheat v. Pfizer, Inc.*, 31 F.3d 340 (5th Cir. 1994) (affirming summary judgment); *Anderson*, 831 F.2d 92 (same); *Zachary v. Dow Corning Corp.*, 884 F. Supp. 1061, 1065 (M.D. La. 1995) (granting summary judgment); *Bealer*, 729 F. Supp. 43 (same); *Calhoun*, 2000 WL 202067 (affirming summary judgment); *Mikell*, 649 So. 2d at 75 (same); *Kinney*, 468 So. 2d 714 (same); *Cobb*, 444 So. 2d 203 (same).

court and the Fifth Circuit illustrate, the courts below took great pains to address all of the arguments raised by Petitioner.

## III. No Circuit Conflict Exists Concerning the Application of Federal Rule of Evidence 407 to Subsequent Prescription Drug Warnings.

There is no conflict between the Fifth Circuit's holding in this case and the Eighth Circuit's decision in *O'Dell v. Hercules, Inc.*, 904 F.2d 1194 (8th Cir. 1990). In footnote 10 of its opinion in this case, the Fifth Circuit noted in *dicta* that changes made to the Lamisil® label subsequent to the Petitioner's injury could not be considered because they constituted a subsequent remedial measure under Fed. R. Evid. 407. This application of Rule 407 is in complete accord with the Eighth Circuit's application of Rule 407 in a similar case involving prescription drugs.

In *DeLuryea v. Winthrop Lab.*, the Eighth Circuit examined the application of Rule 407 in the specific context of subsequent remedial changes in prescription drug labeling. 697 F.2d 222, 229 (8th Cir. 1983). The court concluded that Rule 407 "requires exclusion of evidence of subsequent remedial changes in [a drug manufacturer's] warning literature." *Id.* (relying on *Werner v. Upjohn Co.*, 628 F.2d 848, 859-60 (4th Cir. 1980), *cert. denied*, 449 U.S. 1080 (1981), in which the Fourth Circuit found the application of Rule 407 particularly appropriate in the context of subsequent remedial changes in prescription drug labeling because it encourages "early, unilateral action by the drug companies to improve their warnings" and supports applicable FDA labeling regulations).

Petitioner does not cite — much less address — the Eighth Circuit's opinion in *DeLuryea*. Rather, he cites to *O'Dell*, an Eighth Circuit opinion that does not involve prescription drugs, and which in any case is not inconsistent with the *dicta* in footnote 10 of the Fifth Circuit's opinion in this case. *O'Dell v. Hercules, Inc.*, 904 F.2d 1194 (8th Cir. 1990) (addressing Rule 407 issues in context of chemical exposure case).

## IV. The "Voluntariness" Issue Petitioner Asks This Court To Review Was Not Raised By Petitioner Or Considered By The Courts Below.

Petitioner also relies on the Eight Circuit's opinion in *O'Dell* to support a new argument not made below that "involuntary" remedial measures are not subject to Rule 407. This argument is irrelevant to this case, however, because there was no record evidence or argument of any kind in the courts below that would indicate that subsequent changes to the Lamisil® label were "involuntary." Further, as the Fourth Circuit explained in *Werner*, the unique relationship between FDA and manufacturers of prescription drugs makes any "voluntariness" analysis under Rule 407 inappropriate in prescription drug cases. 628 F.2d at 859-60.

Moreover, because Petitioner did not raise his "voluntariness" argument concerning Fed. R. Evid. 407 in the district court or the Fifth Circuit, neither court addressed this issue. As a general rule, a question presented in the petition for writ of certiorari but not raised in the court of appeals is not properly before the Supreme Court. *See Delta Airlines v. August*, 450 U.S. 346, 362 (1981) (issue of the district judge's alleged abuse of discretion in denying defendants' costs was not properly before the Court because

not raised in the Court of Appeals); *see also Campbell v. Louisiana*, 523 U.S. 392, 403, 118 S. Ct. 1419, 1425 (1998) (refusing to address issue raised by petitioner on certiorari where "neither the Louisiana Supreme Court nor the Louisiana Court of Appeal discussed this contention" and petitioner had "made no effort to meet his burden of showing this issue was properly presented to the Louisiana appellate courts"). In any event, the Fifth Circuit obviously could not have created a split in the circuits on this "voluntariness" issue given that the issue was neither raised nor addressed below.

## V. Petitioner's Allegations of Evidentiary Error Arising from Rule 407's Impeachment Exclusion Do Not Implicate Any Certworthy Issue.

Petitioner's contention that the courts below erred by not admitting subsequent label changes as evidence of impeachment under Rule 407 raises no certworthy issue. It is axiomatic that this Court does not sit as a court of error correction. There was no error below in any event, because the subsequent Lamisil® labels do not contradict any testimony by Novartis or its witnesses. Thus, as the Fifth Circuit and the district court correctly recognized below, such subsequent labeling changes are not admissible under Rule 407. This conclusion is in complete accord with the law of other federal circuits. *See Probus v. K-Mart, Inc.*, 794 F.2d 1207, 1210 (7th Cir. 1986) ("impeachment" exception under Rule 407 cannot be used to argue that subsequent remedial measure "'impeaches' a defendant's contention that he was exercising due care," because to allow such a broad exception would elevate the exception to the rule).

## CONCLUSION

The Fifth Circuit's application of the Louisiana learned intermediary doctrine in this case was correct and uncontroversial. No conflict between the circuits was created. The Petition for Writ of Certiorari should be denied.

Respectfully submitted,

JOY GOLDBERG BRAUN
*Counsel of Record*
ERIC R. NOWAK
SESSIONS, FISHMAN, & NATHAN LLP
*Attorneys for Respondent*
201 St. Charles Avenue
35th Floor
New Orleans, LA 70170
(504) 582-1500